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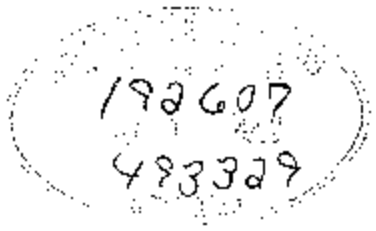
UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION



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

To: The Honorable D. Michael Chappell
Administrative Law Judge

COMPLAINT COUNSEL'S REPLY TO SCHERING PLOUGH'S PROPOSED ECONOMIC AND POLICY FINDINGS

[PUBLIC VERSION]

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Counsel Supporting the Complaint

May 14, 2002

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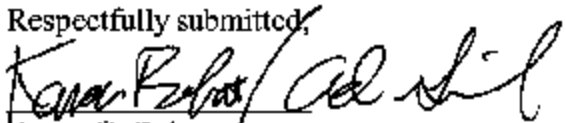
Complaint counsel respectfully submit their reply to Schering-Plough's proposed policy and economic findings. For the convenience of the court, we have reprinted each of proposed findings, followed by complaint counsel's reply. A separate reply brief accompanies these reply findings.

Respectfully submitted,



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INTRODUCTION

Respondent's proposed findings of fact should not be adopted by the Administrative Law Judge. Many of those findings are unsupported by the record, contrary to more reliable evidence, incomplete, misleading, or otherwise unreliable. On the following pages, we have reproduced each of respondent's proposed findings of fact. Complaint counsel's response ("CPRF") follows each finding or group of findings responded to. While we have attempted to address the most important issues posed by the proposed findings, we have not responded to every point made by respondent. Accordingly, the failure to address a particular proposed finding or part thereof does not signify endorsement of the finding, and should not be taken as agreement that the proposed finding be adopted.

The following citation forms are used in these reply findings.

CPRF - Complaint Counsel's Reply Finding

CPF - Complaint Counsel's Proposed Finding of Fact

CX - complaint counsel exhibit

SPX - Schering-Plough exhibit

USX - Upsher-Smith exhibit

Complaint - Complaint of the Federal Trade Commission, issued March 30, 2001.

Schering Answer - Answer of Schering-Plough Corporation, filed April 23, 2001.

Upsher Answer - Answer of Upsher-Smith Laboratories, Inc., filed April 23, 2001

AHP Answer - Answer of American Home Products Corporation, filed April 23, 2001.

Schering First Admissions - Schering-Plough Corporation's Objections and Responses to Complaint Counsel's First Requests for Admissions, filed August 6, 2001.

Schering Second Admissions - Schering-Plough Corporation's Objections and Responses to Complaint Counsel's Revised Second Requests for Admissions, filed November 14, 2001.

Upsher First Admissions - Upsher-Smith's Objections and Responses to Complaint Counsel's First Set of Requests for Admissions, filed Sept. 10, 2001.

Upsher Second Admissions - Upsher-Smith's Objections and Responses to Complaint Counsel's Second Set of Requests for Admissions, filed November12, 2001.

Upsher Third Admissions - Upsher-Smith's Objections and Responses to Complaint Counsel's Revised Third Set of Requests for Admissions, filed September 13, 2001.

Citations to the transcript include the volume, page number, and witness name: Tr. at 1:125 (Goldberg).

Pages of exhibits are referenced by bates number: CX 422 at SP 06 00009.

References to investigational hearing or deposition transcripts that have been included in the trial record as exhibits include the exhibit number, the page and lines of the deposition or investigational hearing transcript, the witness name, and the designation "IH" or "dep": CX 1516 at 40:7-12 (Lauda dep).

Citations to admissions include the designated abbreviation and the paragraph number of the request and response: Schering First Admissions No.1.

In camera material and citations are in italics.

Documents that were admitted subject to the limitation that they were not offered for the truth of the matters asserted are indicated by an asterisk after the exhibit number: SPX 693*.

The investigational hearings of Schering officials that have been admitted against Schering but are used for the purpose of contradicting and impeaching the trial testimony of Upsher's Ian Troup (a purpose which is currently excluded) are marked by a superscript (") following the exhibit number.

AHP documents, depositions, and investigational hearings were admitted subject to the Administrative Law Judge's satisfaction that complaint counsel properly proved a conspiracy and all the required elements under the co-conspirator rule. These documents are marked by a superscript (†) following the exhibit number.

I. MONOPOLY POWER

A. Proof of Monopoly Power is Needed to Determine Whether Settlements Are Anticompetitive

3.1. Complaint counsel's economic expert, Professor Bresnahan, developed his own three-part test to determine whether a patent infringement settlement agreement between a branded firm and a generic firm is anti-competitive: "(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." (CX 751 at 22) (4 Tr. 655-56 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.1:

The proposed finding is incomplete and misleading, to the extent it suggests that the test employed by Professor Bresnahan was a mere invention of his, and does not rest on sound economic bases. To the contrary, as Professor Bresnahan testified: "The three-part test is the economist's usual definition of anti-competitive contracts but applied to the particular context . . . of these agreements or agreements like these . . . ." Tr. at 3:419 (Bresnahan).

3.2. The first prong of Professor Bresnahan's test, proof of monopoly power, is essential to determining whether the agreements are anticompetitive. (25 Tr. 6198 (Addanki)). Professor Bresnahan concedes that the first prong of the test would not be met if neither Upsher nor Schering were a monopolist as of June 17, 1997. (4 Tr. 661 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.2:

The proposed finding is incomplete. As Dr. Kerr, Upsher's expert acknowledged, the first prong of Complaint Counsel's test asks whether the pioneer has market power. While this would seem to be a reasonable question, in the context it is proposed, it is not. It can have only one answer. If a pioneer's patent did not provide any market power, there would be no reason for a generic to challenge the patent. Tr. at 27:6571 (Kerr).

3.3. Schering's economic expert, Dr. Addanki, agreed with Professor Bresnahan that the necessary first step of analysis is to determine whether the branded firm had monopoly power at the time of the settlement. (24 Tr. 5680 (Addanki)) (SPX 2065) (demonstrative) (4 Tr. 6659-64 (Bresnahan)). Dr. Addanki agreed with Professor Bresnahan that only if the branded firm had monopoly power could a settlement be anticompetitive. (24 Tr. 5680 (Addanki)) (SPX 2065) (demonstrative). Dr. Addanki's analysis of whether there is monopoly power would also encompass whether there was a threat to monopoly power—the first two prongs of the Bresnahan test. (24 Tr. 5680 (Addanki)) (SPX 2065) (demonstrative).

Complaint Counsel's Response to Finding No. 3.3:

Complaint counsel has no specific response.

B. Evidence Related to Monopoly Power

1. Relevant Product Market

3.4. The first step necessary to determine whether a firm has monopoly power is to determine the relevant market in which the firm competes, and to ascertain the competitive

constraints operating on the firm in that market. (Addanki 24 Tr. 5682). This requires one to examine the conditions in the relevant market, the firm's market share, barriers to entry, and the firm's capacity to expand output. (24 Tr. 5682 (Addanki)).

Complaint Counsel's Response to Finding No. 3.4:

The proposed finding is contrary to more reliable evidence. There is more than one way to determine if a firm has monopoly power. One way to determine if a firm has market power is to define the relevant market and then to evaluate the competitive constraints operating on the firm in that market. Using this methodology, economists define markets as a precursor to determining whether a firm has monopoly power, "[e]conomists define markets in order to establish the area within which competition will decrease prices." Tr. at 6:1222 (Bresnahan).

However, an economist may also directly assess pricing affects of the product in question. In this case there was direct evidence of the forecasted and actual impact of generic entry on the ability of Schering to control the prices for its K-Dur 20 product. Until there was entry of another 20 mEq potassium chloride tablet or capsule into the market, a product that was rated an AB generic to the K-Dur 20 by the FDA, Schering was able to increase its prices relative to other potassium chloride products while at the same time increasing its share of the total sales of potassium chloride products. *See* CPF 972 - 984. Schering, Upsher and AHP all recognized that this pricing power would continue until the entry of an AB rated generic 20 mEq version of K-Dur 20 into the market, and that entry of an AB rated generic 20 mEq version of K-Dur 20 into the market would end that pricing power. *See* CPF 949 - 971. When Upsher finally entered

the market with its Klor Con M20 20 mEq generic version of K-Dur 20, the pricing power of Schering, the ability to maintain a high price and expand its share of total potassium chloride sales, ended. *See* CPF 988 - 992. Such direct evidence of market power eliminates the need for the economist to first define the relevant market to demonstrate market power. Tr. at 6:1224 - 1225 (Bresnahan) (use of direct evidence for identifying market power is stronger than other methods in this case).

3.5. This monopoly power "screen" is essential to get through before doing anything else to evaluate the agreement. (25 Tr. 6198 (Addanki)).

Complaint Counsel's Response to Finding No. 3.5:

The proposed finding is incomplete and misleading. While a monopoly power "screen" is essential to get through before evaluating the settlement agreements between Schering and Upsher and between Schering and AHP, the monopoly power screen need not done by defining a relevant market and then looking at market shares, conditions of entry and expansion. Monopoly power is the power to charge a supra-competitive price in the absence of competition that would constrain the monopolist's price. CPF. 1131. If one can directly assess pricing affects to determine that there is monopoly power, that will satisfy the need to perform a monopoly power "screen". Tr. at 6:1224 - 1225 (Bresnahan) (use of direct evidence for identifying market power is directly on point and stronger than other methods in this case).

a. Determining the relevant product market requires an examination of the substitutability of products

3.6. The relevant market must include all products reasonably interchangeable by consumers for the same purposes. (6 Tr. 1171-72 (Bresnahan)). Accordingly, the product market must be defined based on the degree of substitution among products. (24 Tr. 5682-83 (Addanki)). One must identify all of the products that reasonably could be substituted for the product at issue - here, the products that could be substituted for K-Dur 20. (*Id.* at 5682-83). This is the set of products that will competitively constrain what Schering can do in the marketplace. (*Id.* 5683).

Complaint Counsel's Response to Finding No. 3.6:

The proposed finding is incomplete and misleading. The relevant market must include products reasonably interchangeable by consumers at competitive prices. If at a competitive price for K-Dur 20, consumers would not consider potassium chloride products that are not 20 mEq tablets or capsules reasonably interchangeable for K-Dur 20, (for reasons of convenience, safety, or whatever) then the relevant market that contains K-Dur 20 would not also include the products that are not 20 mEq potassium chloride tables or capsules. However, if there were a singe seller of 20 mEq potassium chloride tablets or capsules, that seller would then have an incentive to raise prices. This is because the other products, not being reasonably interchangeable at competitive prices, would not take away so many sales from the 20 mEq product to make such a price increase unprofitable. The single seller of 20 mEq potassium chloride would find it profitable to raise prices until consumers just begin to find other products reasonably interchangeable.

If one measured the interchangeability at the monopoly prices, in order to determine interchangeability one would fall into the "cellophane trap" or "cellophane fallacy" and define the market too broadly. Measuring the interchangeability of potassium chloride products at prices that reflect Schering's monopoly pricing, after it began raising prices above other potassium chloride products, while at the same time it was increasing its share of sales, would be falling it the "cellophane trap" or "cellophane fallacy." *See* CPF 1086-1089.

3.7. Determination of interchangeability requires one to determine the purpose for which a product is used, and to identify all the other products that could be used for the same purpose. (*Id.* 5683). An examination is then made about whether these other products differ materially from the product at issue, and if so, whether the differences have any implications for whether those products could substitute for the product at issue. (*Id.* 5684).

Complaint Counsel's Response to Finding No. 3.7:

The proposed finding is incomplete and misleading. In order to determine interchangeability one must avoid the "cellophane trap" by mechanical application of substitutability. *See* CPRF 3.6; CPF 1086-1089.

3.8. Cross-elasticity of demand is another measure of substitutability. According to Professor Bresnahan, cross-elasticity of demand between a 20 mEq potassium chloride product and a 10 mEq potassium chloride product exists where a change in the price of the 20 mEq product affects the quantity demanded of the 10 mEq product. (4 Tr. 688 (Bresnahan)).

Similarly, if there were an observed increase in the demand for 20 mEq powders due to a higher price for 20 mEq tablets, cross-elasticity of demand would be shown between the powder and the tablets. (4 Tr. 689 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.8:

The proposed finding is incomplete and misleading. As the proposed finding notes, cross-elasticity of demand is just a tool used to measure substitution to determine whether two products are reasonably interchangeable. As such, one must be careful at what price level the cross-elasticity of demand is measured in order to avoid the "cellophane trap" by mechanical application of substitutability. *See* CPF 1086-1089.

3.9. 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. (24 Tr. 5684 (Addanki)). Indeed, Professor Bresnahan himself 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. (*Id.*; 4 Tr. 675 (Bresnahan); 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. (24 Tr. 5684 (Addanki)). There may be other substitutes. (*Id.* 5684).

Complaint Counsel's Response to Finding No. 3.9:

The proposed finding is incomplete, misleading, and irrelevant. Product markets are defined by which products are reasonably interchangeable with one another at the appropriate competitive prices. *See* CPRF 3.6. Whether a branded drug and the generic

pharmaceuticals that "AB-rated" to that branded drug is sufficient to define the antitrust product market is an empirical question. If consumers find that the only product that is reasonably interchangeable to the branded drug is AB rated generic products, than the product market for antitrust purposes is the branded product and the AB rated generic products.

This finding is irrelevant because the facts of this case show that Schering had market power with K-Dur 20 without going through the intermediate step of defining the relevant market and measuring such things as market share and entry conditions. Schering was able to control (i.e. increase) the price of K-Dur 20, unconstrained by other potassium chloride products, until the introduction of an AB rated generic product onto the market in September 2001. *See* CPF 972-987, 997-1002 (showing that K-Dur 20's prices, sales, and share of sales increased annually, and that K-Dur 20's generic substitution rate was extremely low compared to other potassium chloride brands, despite K-Dur 20's substantially higher price compared to those generics); CPF 988-92 (entry of a 20mEq generic eroded K-Dur's sales volume and the 20mEq average price).

3.10. The existence of a patent does also not necessarily define the product market. (Addanki 5685). Patents describe only the technological uniqueness of a product. They do not say anything about whether products that may not be technologically identical would nevertheless be substitutes for one another. (*Id*).

Complaint Counsel's Response to Finding No. 3.10:

The proposed finding is incomplete, misleading, and irrelevant. Product markets are defined by which products are reasonably interchangeable with one another at the appropriate competitive prices. *See* CPRF 3.6. Whether the patented characteristic of a product so differentiates the product so that only products with the patented characteristic should be included in the antitrust product market is an empirical question. If consumers find that the only products that have the patented characteristic are reasonably interchangeable, then those products define the antitrust product market.

This finding is irrelevant because the facts of this case show that Schering had market power with K-Dur 20 without going through the intermediate step of defining the relevant market and measuring such things as market share and entry conditions. Schering was able to control (i.e. increase) the price of K-Dur 20, unconstrained by other potassium chloride products, until the introduction of an AB rated generic product onto the market in September 2001. *See* CPF 972-987, 997-1002 (showing that K-Dur 20's prices, sales, and share of sales increased annually, and that K-Dur 20's generic substitution rate was extremely low compared to other potassium chloride brands, despite K-Dur 20's substantially higher price compared to those generics); CPF 988-92 (entry of a 20mEq generic eroded K-Dur's sales volume and the 20mEq average price).

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

3.11. K-Dur is a potassium chloride product marketed by Schering. (15 Tr. 3410-11

(Russo)). K-Dur is primarily used to treat potassium depletion in coronary artery disease patients. (*Id.*). 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. (*Id.*; 1 Tr. 125-26 (Goldberg)).

Complaint Counsel's Response to Finding No. 3.11:

Complaint counsel has no specific response.

3.12. K-Dur is marketed in 10 mEq and 20 mEq dosage strengths. (15 Tr. 3411 (Russo)). The 10 mEq and 20 mEq labels denote the amount of potassium within the tablet. (*Id.* at 3415).

Complaint Counsel's Response to Finding No.3.12:

Complaint counsel has no specific response.

3.13. There are at least 23 potassium supplements on the market. (*Id.* at 3414) (SPX 2209-31) (demonstrative); (CX 17). Two Schering products, K-Dur 10 and K-Dur 20, are part of this group of 23 potassium chloride supplements. (15 Tr. 3414 (Russo)) (SPX 2209-10) (demonstrative). All 23 of these products compete against each other in the same market. (15 Tr. 3415 (Russo)). Some of the products that Schering considered to be competitive with K-Dur include Micro-K, Slow K, K-Tab, Klor Con 8 and Klor Con 10, generic KCl tablets and capsules, as well as "other tablets and capsules." (CX 1480 at SP 89826) (25 Tr. 6200 (Addanki)). Schering's documents list a number of other competing products in that market. (6 Tr. 1170 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.13:

The proposed finding is misleading. Economic data, as well as Schering's own data, shows that the potassium supplement products that are not 20 mEq tablets and capsules, and are not AB rated to K-Dur 20 do not constrain Schering's ability to control (i.e. increase) its prices. *See* CRPF 3.28; CRPF 3.29; CRPF 3.38; CRPF 3.39; CRPF 3.60. In order to determine interchangeability one must avoid the "cellophane trap" by mechanical application of substitutability. *See* CPRF 3.6; CPF 1086-1089.

3.14. 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) (5 Tr. 889-90 (Bresnahan)). Complaint counsel's own witness testified that in 1993 and 1994, there were at least 15 competing potassium products, some branded and some generic. (2 Tr. 226-28, 232 (Teagarden)); *see also* USX 125; USX 131 at Merck-Medco 000206).

Complaint Counsel's Response to Finding No. 3.14:

The proposed finding is misleading. Industry data, as well as Schering's own documents, show that the potassium supplement products that are not 20 mEq tablets and capsules, and are not AB rated to K-Dur 20 do not constrain Schering's ability to control (i.e. increase) its prices. *See* CPF 972-987, 997-1002 (showing that K-Dur 20's prices, sales, and share of sales increased annually, and that K-Dur 20's generic substitution rate was extremely low compared to other potassium chloride brands, despite K-Dur 20's

substantially higher price compared to those generics). In order to determine interchangeability one must avoid the "cellophane trap" by mechanical application of substitutability. *See* CPRF 3.6; CPF 1086-1089.

3.15. Managed health care offers many choices of oral potassium chloride supplements. As of October 2001, there were numerous branded and generic potassium chloride products on United Healthcare's Preferred Drug List. (1 Tr. 126 (Goldberg)); (CX 55). In fact, there were at least 24 different combinations of brand and generic potassium chloride products listed on the 2001 United Healthcare Preferred Drug List. (1 Tr. 154 (Goldberg)) (USX 277). There are several generic manufacturers that make different dosages of potassium chloride products. (1 Tr. 165 (Goldberg)). These potassium chloride products vary according to dosage and form. (1 Tr. 127 (Goldberg)). United Healthcare's Preferred Drug List includes liquid, effervescent tablets, regular tablets and capsule forms of potassium chloride. (1 Tr. 127 (Goldberg))

Complaint Counsel's Response to Finding No. 3.15:

This proposed finding is irrelevant. Industry data, as well as Schering's own documents, show that the potassium supplement products that are not 20 mEq tablets and capsules, and are not AB rated to K-Dur 20 do not constrain Schering's ability to control (i.e. increase) its prices. *See* CPF 972-987, 997-1002 (showing that K-Dur 20's prices, sales, and share of sales increased annually, and that K-Dur 20's generic substitution rate was extremely low compared to other potassium chloride brands, despite K-Dur 20's substantially higher price compared to those generics). In order to determine interchangeability one must avoid the "cellophane trap" by mechanical application of

substitutability. *See* CPRF 3.6; CPF 1086-1089.

3.16. As of 2001, there were numerous branded and generic potassium chloride products on Merck-Medco's formulary. (3 Tr. 207, 216-17 (Teagarden)); (CX 56); (CX 57). For example, there were a minimum of two potassium chloride bicarbonate citric acid products available, one branded and the other generic. (2 Tr. 216-17 (Teagarden)) (CX 57). Merck-Medco's 2001 formulary lists numerous potassium supplements that are available in tablet, powder and solution dosage forms. (2 Tr. 207 (Teagarden)) (CX 56).

Complaint Counsel's Response to Finding No. 3.16:

This proposed finding is irrelevant. Industry data, as well as Schering's own documents, show that the potassium supplement products that are not 20 mEq tablets and capsules, and are not AB rated to K-Dur 20 do not constrain Schering's ability to control (i.e. increase) its prices. *See* CPF 972-987, 997-1002 (showing that K-Dur 20's prices, sales, and share of sales increased annually, and that K-Dur 20's generic substitution rate was extremely low compared to other potassium chloride brands, despite K-Dur 20's substantially higher price compared to those generics). In order to determine interchangeability one must avoid the "cellophane trap" by mechanical application of substitutability. *See* CPRF 3.6; CPF 1086-1089.

3.17. Medco, a pharmacy benefit manager and Merck-Medco's predecessor, regards 10 mEq and 20 mEq potassium chloride products to be "competing." (2 Tr. 226 (Teagarden)); (USX 131 at Merck-Medco 000206).

Complaint Counsel's Response to Finding No. 3.17:

This proposed finding is irrelevant. Industry data, as well as Schering's own documents, show that the potassium supplement products that are not 20 mEq tablets and capsules, and are not AB rated to K-Dur 20 do not constrain Schering's ability to control (i.e. increase) its prices. *See* CPF 972-987, 997-1002 (showing that K-Dur 20's prices, sales, and share of sales increased annually, and that K-Dur 20's generic substitution rate was extremely low compared to other potassium chloride brands, despite K-Dur 20's substantially higher price compared to those generics). In order to determine interchangeability one must avoid the "cellophane trap" by mechanical application of substitutability. *See* CPRF 3.6; CPF 1086-1089.

3.18. The economists for both complaint counsel and Schering agreed that there were many substitute products for K-Dur 20 during the relevant period. Dr. Addanki found that many other potassium chloride products were substitutable for K-Dur 20. (24 Tr. 5701 (Addanki)). Professor Bresnahan agreed that there was some substitution and interchangeability of use between K-Dur 20 and other potassium chloride products, including generics. (4 Tr. 744 (Bresnahan); 5 Tr. 853 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.18:

The proposed finding is misleading, contradicted by other evidence, and irrelevant. The issue in defining antitrust markets is not whether there exist substitute products, but whether the products are reasonably interchangeable in the views of

consumers. Tr. at 6:1173-74 (Bresnahan). The available data on the substitution rates for branded potassium chloride products shows that for K-Dur 20, unlike other branded potassium chloride products, consumers do not view other products as reasonably interchangeable. During a time when Schering was increasing the price of K-Dur 20 relative to other potassium chloride products, almost no prescriptions for K-Dur 20 were filled by other than K-Dur 20, while over half the prescriptions for two other branded potassium chloride products were being filled by generic potassium chloride products.

Rate of Substitution of Prescriptions for Potassium Chloride Products:

Product	1996	1997	1998	1999	2000
K-Dur 20	0.11%	0.10%	0.06%	0.06%	0.06%
Micro-K-10	71.9%	78.2%	82.2%	84.9%	87.2%
K-Tab	59.3%	64.9%	69.3%	74.4%	79.4%

Source: CPF 1001.

c. Potassium chloride products are therapeutically equivalent

3.19. All potassium chloride supplements are used to treat the same condition, hypokalemia. (1 Tr. 125-26 (Goldberg); 15 Tr. 3411 (Russo)).

Complaint Counsel's Response to Finding No. 319:

This proposed finding is irrelevant. The issue in defining antitrust markets is not whether two products are used to treat the same condition, but whether the two products are reasonably interchangeable in the view of consumers. Tr. at 6:1171-72 (Bresnahan). Industry data, as well as Schering's own documents, show that the potassium supplement

products that are not 20 mEq tablets and capsules, and are not AB rated to K-Dur 20 are not sufficiently reasonably interchangeable with K-Dur 20 and do not constrain Schering's ability to control (i.e. increase) its prices. *See* CPF 972-987, 997-1002 (showing that K-Dur 20's prices, sales, and share of sales increased annually, and that K-Dur 20's generic substitution rate was extremely low compared to other potassium chloride brands, despite K-Dur 20's substantially higher price compared to those generics). In order to determine interchangeability one must avoid the "cellophane trap" by mechanical application of substitutability. *See* CPRF 3.6; CPF 1086-1089.

3.20. If a physician prescribes a specific amount of potassium, any potassium chloride product would be effective. (21 Tr. 4951-52 (Freese)). A prescription for 20 mEq of potassium could be satisfied with a potassium chloride powder, effervescent, or liquid. (*Id.* at 4953-54) (USX 410 at Upsher-Smith FTC-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. (21 Tr. 4956(Freese)).

Complaint Counsel's Response to Finding No. 3.20:

The fact that any potassium chloride product would be effective in getting a patient an amount of potassium chloride is irrelevant. The issue in defining antitrust markets is not whether two products are effective in getting a patient an amount of potassium chloride, but whether the two products are reasonably interchangeable in the view of consumers. Tr. at 6:1171-72 (Bresnahan). Industry data, as well as Schering's own documents, show that the potassium supplement products that are not 20 mEq tablets

and capsules, and are not AB rated to K-Dur 20 are not sufficiently reasonably interchangeable with K-Dur 20 and do not constrain Schering's ability to control (i.e. increase) its prices. *See* CPF 972-987, 997-1002 (showing that K-Dur 20's prices, sales, and share of sales increased annually, and that K-Dur 20's generic substitution rate was extremely low compared to other potassium chloride brands, despite K-Dur 20's substantially higher price compared to those generics).

The fact that all potassium chloride products are therapeutically interchangeable, allows a physician to prescribe potassium chloride to a patient in whatever product form that is appropriate for that patient. That may explain why there are so many different forms of potassium chloride products. However the proposed finding is contradicted by other evidence when it asserts that a pharmacist may dispense potassium chloride in whatever form is appropriate for the patient. The pharmacist is not permitted to change the form of the potassium chloride that was prescribed by the physician, without the later's permission. CPF 34, 36 (explaining that pharmacists cannot substitute non-AB rated generics for brands, which would include different dosage forms or strengths of potassium chloride, without physician approval).

3.21. At maintenance, a physician will typically prescribe approximately 40 mEqs of potassium per day. (15 Tr. 3423 (Russo)). If a doctor writes a prescription for K-Dur 20, a patient will take two tablets, twice a day and with meals. (*Id.* at 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. (*Id.* at 3424).

Complaint Counsel's Response to Finding No. 3.21:

The proposed finding is incomplete. Evidence shows that K-Dur 20 is preferred because of its dosing advantages, is rarely substituted with 10 mEq products, and is perceived as not interchangeable with other dosage strengths of potassium chloride. *See* CPF 1043-1069. Mr. Goldberg of United Healthcare testified that there were good reasons relating to patient compliance and convenience for discouraging the substitution of, for example, two 10 mEq tablets for one K-Dur 20 mEq tablet, and that United Healthcare had never considered suggesting this to its participating physicians or patient members. Tr. at 1:169-70 (Goldberg).

3.22. 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. (20 Tr. 4689-90 (Dritsas) (CX 740).

Complaint Counsel's Response to Finding No. 3.22:

The proposed finding is incomplete and misleading. Therapeutic substitutions of non-AB related products cannot be made automatically at the pharmacy level, and result in switching costs involved in getting physicians to make them. *See* CPF 1011-1013; Tr. at 20:4634-4635 (Dritsas). Empirical data shows that K-Dur 20 had a very low rate of substitution compared to other branded potassium chloride products. CPRF 3.18.

3.23. K-Dur 20's 20 mEq dosage does not give it a therapeutic advantage over other

potassium chloride products. (15 Tr. 3421 (Russo)).

Complaint Counsel's Response to Finding No. 3.23:

The proposed finding is contradicted by other evidence. As shown in its own marketing documents, Schering was well aware of the therapeutic advantages K-Dur 20 offered over other potassium chloride products. CX 2 at SP 003043 (K-Dur 20 mEq Review) (stating greater patient compliance and safety with K-Dur 20); CX 1549 at 30:15-19 (DiLascia dep.) (20 mEq dose was sufficient for prophylaxis against hypokalemia); *See also* CPF 1046-1070. In fact, Schering stressed its therapeutic advantages in its promotion of K-Dur 20. Tr. at 25:6020-21, 25:6023 (Addanki).

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

Complaint Counsel's Response to Finding No. 3.24:

The proposed finding is irrelevant and misleading. Therapeutic interchange merely means that the two products contain the same amount of the active ingredient. Therapeutic interchange does not mean that two products are reasonably interchangeable. K-Dur 20 was rarely substituted with Klor Con 10 at the pharmacy level. *See* CPRF 3.18; *see also* CPF 1016-1023 (excluded evidence). Moreover, Upsher's marketing plan to convince physicians to change their prescribing habits failed to convert substantial K-Dur 20 sales to Klor Con 10. CPF 1024-1027.

3.25. Two 10 mEq tablets would effectively release in a patient's stomach at approximately the same rate as one 20 mEq tablet. (1 Tr. 174-75 (Goldberg)). 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. (20 Tr. 4660-61 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.25:

The proposed finding is misleading. First, a pharmacist may not simply give a patient two Klor Con 10 tablets instead of one K-Dur 20 tablet, Klor Con 10 is not an AB rated generic to K-Dur 20. Such a substitution would require intervention of the prescribing physician. CPF 1016-18 (excluded evidence); *see also* CPF 34, 36 (explaining that pharmacists cannot substitute non-AB rated generics for brands, which would include different dosage forms or strengths of potassium chloride, without physician approval). Moreover, a 10 mEq tablet has less potassium then a 20 mEq, and a patient would have to take more doses of 10 mEq tablets and have less flexibility in dosing then a patient taking the 20 mEq tablet. This greatly improves convenience to the patient and increases patient compliance. *See* CPF 1057-1067. That is one of the main reasons why the market continued to trend toward K-Dur 20, (CPF 960), and K-Dur 20 had such a low substitution rate. CPRF 3.18. Mr. Goldberg of United Healthcare testified that there were good reasons relating to patient compliance and convenience for discouraging the substitution of, for example, two 10 mEq tablets for one K-Dur 20 mEq tablet, and that United Healthcare had never considered suggesting this to its participating physicians or patient members. Tr. at 1:169-70 (Goldberg).

3.26. 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 4693-94) (USX 1549 USL 13859). In 2000, Upsher marketed its Klor Con products as therapeutically substitutable for both Micro-K and K-Dur. (Dritsas 4775-76) (USX 410 at Upsher-Smith FTC-190322-23, 190347).

Complaint Counsel's Response to Finding No. 3.26:

The proposed is contrary to more reliable evidence and is irrelevant. The issue in defining antitrust markets is not whether two products are therapeutically equivalent and comparable, but whether the two products are reasonably interchangeable in the view of consumers. Tr. at 6:1171-72 (Bresnahan). Industry data, as well as Schering's own documents, show that the potassium supplement products that are not 20 mEq tablets and capsules, and are not AB rated to K-Dur 20 are not sufficiently reasonably interchangeable with K-Dur 20 and do not constrain Schering's ability to control (i.e. increase) its prices. *See* CPF 972-987, 997-1002 (showing that K-Dur 20's prices, sales, and share of sales increased annually, and that K-Dur 20's generic substitution rate was extremely low compared to other potassium chloride brands, despite K-Dur 20's substantially higher price compared to those generics). In order to determine interchangeability one must avoid the "cellophane trap" by mechanical application of substitutability. *See* CPRF 3.6; CPF 1086-1089.

K-Dur 20 was distinct from Klor Con potassium products because of its novel microencapsulation technology, which reduced gastrointestinal irritation that may occur

with the delivery of potassium chloride. CPF 1049-1056. Schering marketed this aspect of K-Dur as a therapeutic advantage. CPF 1069-1070; CPRF 3.23; CPRF 3.40.

3.27. Based on this evidence, Dr. Addanki concluded that there were no therapeutic differences among potassium supplements. (24 Tr. 5689-90 (Addanki)). For example, Dr. Addanki relied in part for this conclusion on the fact that Upsher's salespeople were trained to promote the taking of two Klor Con 10 tablets for one K-Dur 20 tablet as providing the same therapeutic effect. (20 Tr. 4622 (Freese)) (24 Tr. 5691 (Addanki)). Dr. Addanki also relied on Schering documents that suggested that decision-makers were not prescribing K-Dur 20 because of its therapeutic attributes, but for other reasons. (24 Tr. 5691 (Addanki) (CX 13).

Complaint Counsel's Response to Finding No. 3.27:

The proposed finding is irrelevant and incomplete. The issue in defining antitrust markets is not whether there are therapeutic differences between two products, but whether the two products are reasonably interchangeable in the view of consumers. 6 Tr. at 1171-1172 (Bresnahan). Industry data, as well as Schering's own documents, show that the potassium supplement products that are not 20 mEq tablets and capsules, and are not AB rated to K-Dur 20 are not sufficiently reasonably interchangeable with K-Dur 20 and do not constrain Schering's ability to control (i.e. increase) its prices. *See* CPF 972-987, 997-1002 (showing that K-Dur 20's prices, sales, and share of sales increased annually, and that K-Dur 20's generic substitution rate was extremely low compared to other potassium chloride brands, despite K-Dur 20's substantially higher price compared to those generics). In order to determine interchangeability one must avoid the

"cellophane trap" by mechanical application of substitutability. *See* CPRF 3.6; CPF 1086-1089.

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

3.28. According to complaint counsel's own witnesses, oral potassium chloride products are therapeutically equivalent. Merck-Medco has consistently regarded potassium chloride products with different delivery systems as clinically equivalent and therefore interchangeable. (2 Tr. 249-50 (Teagarden); (USX 123; USX 124; USX 125).

Complaint Counsel's Response to Finding No. 3.28:

The proposed finding is misleading. First, the oral potassium chloride products referred to in both the testimony and exhibits are not 20 mEq potassium chloride supplements. They refer to 8 or 10 mEq potassium chloride products. Tr. at 2: 249-50; USX 123; USX 124; USX 125 at Merck-Medco 000169. Second, Merck-Medco only regarded products with the same dosage strength as clinically equivalent and interchangeable. For example, Merck-Medco describes as interchangeable with each other only potassium chloride tablets and capsules within the 10 mEq category. USX 124 at Merck-Medco 000155; USX 125 at Merck-Medco 000167. Merck-Medco also only describes as interchangeable and clinically equivalent with each other only tablets and capsules within the 8 mEq category of potassium chloride products. USX 124 at Merck-Medco 000157. Only products with the same dosage form and strength, such as 20 mEq tablets and capsules, are interchangeable to Merck-Medco.

3.29. Merck-Medco equates microencapsulated tablets and capsules with wax matrix potassium chloride products. (2 Tr. 232); 247-48, 250 (Teagarden)) (USX 123; USX 124; USX 125). 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. (2 Tr. 233-34, 237-38, 240, 243, 255-56 (Teagarden); 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. (2 Tr. 234, 240, 243-44, 256 (Teagarden)) (USX 125; USX 127; USX 128; USX 690).

Complaint Counsel's Response to Finding No. 3.29:

The proposed finding is misleading. The exhibits cited in the finding do not describe branded and generic liquids, sustained release tablets and capsules, effervescent tablets, and powder potassium chloride supplements as alternative products substitutable for one another. In fact, they clearly limit substitutability to products with the same dosage strength and form – for example, 8 mEq tablets and capsules are listed as interchangeable with each other. USX 124 at Merck-Medco 000157 and 000169; Tr. at 20: 4846-47 (Dritsas) (other forms of potassium chloride cannot be substituted automatically for a K-Dur 20 tablet). The exhibits never describe products of different strengths, such as an 8 mEq or 10 mEq, as substitutable amongst each other. USX 125 at Merck-Medco 000167; Tr. at 20: 4846 (Dritsas) (equivalent dosages of products of other strengths cannot be substituted automatically for K-Dur 20). To show substitutability between different forms and strengths of potassium chloride, Schering relies on pages of Merck-Medco formularies that list all electrolytes together. The formularies in no way

imply that all electrolytes are interchangeable with each other; in fact, the formularies on the same pages and others clearly divide the products by strength and form, and base interchangeability on strength and form. USX 125; USX 127; USX 128; USX 690.

3.30. All the potassium chloride products on Merck-Medco's 2001 formulary are listed in the same therapeutical class. (2 Tr. 223-24 (Teagarden)) (USX 131).

Complaint Counsel's Response to Finding No. 3.30:

The proposed finding is misleading. *See* CPRF 3.29.

3.31. All the oral potassium chloride products on United Healthcare's Preferred Drug List are therapeutically equivalent. (1 Tr. 144-45 (Goldberg)).

Complaint Counsel's Response to Finding No. 3.31:

This proposed finding is irrelevant and misleading. What is relevant is not whether other forms of potassium chloride are therapeutically equivalent to Schering's K-Dur 20, but whether they can constrain Schering's pricing and the evidence is that forms of potassium chloride other than 20 mEq tablets and capsules cannot prevent Schering from exercising market power. *See* CPF 972-987, 997-1002 (showing that K-Dur 20's prices, sales, and share of sales increased annually, and that K-Dur 20's generic substitution rate was extremely low compared to other potassium chloride brands, despite K-Dur 20's substantially higher price compared to those generics).

3.32. Decision-makers at HMOs do not place a premium on K-Dur's delivery system or

dosage form. (CX 13 at SP 003045) (24 Tr. 5691 (Addanki)).

Complaint Counsel's Response to Finding No. 3.32:

The proposed finding is incomplete and misleading. The increased safety provided by Schering's delivery system, and ease of dosing and resulting greater patient compliance, made K-Dur very attractive to physicians and their patients. *See* CPF 1049-1070. This was reflected in K-Dur's dominant share of sales amongst all other potassium chloride products. CPF 1071-1076.

3.33. Physicians viewed K-Dur 20 as a product for which there were numerous other alternatives. (20 Tr. 4834 (Dritsas)). Indeed, in 1995, 71 percent of the prescriptions for potassium chloride supplementation were being written for products other than K-Dur 20. (25 Tr. 6174 (Addanki)) (CX 13). As of August 1997, 6 out of 10 potassium chloride prescriptions were for something other than K-Dur 20. (7 Tr. 1279 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.33:

The proposed finding is incomplete and misleading. K-Dur 20's share of all dollar sales of potassium chloride products was much higher than its share of all prescriptions, reflecting the differentiation of K-Dur 20 from other products and its higher price. From 1997 to 2000, K-Dur 20's share of total prescriptions as well as its share of total dollar sales of potassium chloride products continued to increase as Schering raised its price relative to other potassium chloride products. CPF 1076.

3.34. A company could compete with K-Dur 20 simply by convincing a physician to

change his prescribing habits. (20 Tr. 4690 (Dritsas)). Prescriptions for potassium chloride were filled with all the various forms of available potassium products. (*Id.* at 4779).

Complaint Counsel's Response to Finding No. 3.34:

The proposed finding is contradicted by more reliable evidence. Upsher's experience with attempting to shift physician prescriptions from K-Dur 20 to Klor Con 10 demonstrates that convincing physicians to change their prescribing habits is difficult. *See* CPF 1024-1028. Also, the evidence shows that, while prescriptions for potassium chloride products other than K-Dur 20 were filled with various generic products, there was very little substitution for K-Dur 20 at the pharmacy level. *See* CPF 1000-1023 (regarding automatic and therapeutic substitution).

3.35. [redacted]

Complaint Counsel's Response to Finding No. 3.35:

Complaint counsel has no specific response.

3.36. There was significant substitution back and forth between Klor Con 10 and K-Dur 20. (20 Tr. 4752 (Dritsas)) (24 Tr. 5702 (Addanki)).

Complaint Counsel's Response to Finding No. 3.36:

The proposed finding not supported by the evidence. Before September 2001, K-Dur 20's generic substitution rate was, at most, 0.11% – much lower than other branded potassium products. CPF 1001. Schering's own documents show that K-Dur 20 had an

unusually low substitution rate. (CX 13 at SP 003044 (Memo, K-Dur Long Term Strategy, March 8, 1995) ("K-Dur 20 enjoys a substitution rate of only 1%"); *see also* CPF 1002. Also, Dr. Addanki's assertions as to the significant substitution of K-Dur 20 ignore the relevant data. CPF 1116-1118.

3.37. Pharmacists were substituting two Klor Con 10s for one K-Dur 20. (20 Tr. 4834 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.37:

The proposed finding is not supported by the evidence. K-Dur 20 was substituted at a very low rate. CPF 1001-1002. Furthermore, the sales and prescriptions of K-Dur 20 increased during the same period that K-Dur 20's relative prices increased, proving that consumers did not view K-Dur 20 as reasonably interchangeable with other potassium chloride supplements. *See* CPF 973, 974, 979, 981, 982.

3.38. Dr. Addanki therefore concluded that differences between oral potassium chloride products did not appear to be material or to affect substitutability between them. (24 Tr. 5701 (Addanki). Thus, the entire set of potassium chloride products that were taken orally were substitutes for one another and for K-Dur 20. (24 Tr. 5700-01 (Addanki)).

Complaint Counsel's Response to Finding No. 3.38:

The proposed finding is not supported by the evidence. Substitution for K-Dur 20 was very low. CPF 1001-1002. Furthermore, the sales and prescriptions of K-Dur 20 increased during the same period that K-Dur 20's relative prices increased, proving that

consumers did not view K-Dur 20 as interchangeable with other potassium chloride supplements. *See* CPF 973, 974, 979, 981, 982.

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

3.39. Schering and Upsher business documents and the testimony from the parties' executives are an important indicator of the product market definition. (4 Tr. 680-81 (Bresnahan); 34 Tr. 8128-8129 (Bresnahan)).

Complaint Counsel's Response to Proposed Finding 3.39:

The proposed finding is incomplete, misleading, and irrelevant. The proposed finding is incomplete and misleading because while such information may be important in determining a product market definition, one should not simply use what marketing documents and executives define as the market to define the market. Tr. at 34:8010-11 (explaining use of such evidence as part of "cellophane fallacy"). One can rely on marketing documents, however. *See* Tr. at 34:8010 (Bresnahan) (testifying one can rely on such documents in analyzing generic substitution, for example), 8055-56 (testifying that while marketing documents are useful, it is not accurate to simply use what the marketing people define as the market- they are using the word differently than economists); *see, e.g.,* Tr. 3:429-32, 454-55, 488-89 (Bresnahan) (using marketing documents and information from marketing employees only as part of larger economic analysis). Schering internal documents showed that Schering was primarily concerned with the threat to K-Dur 20 posed from an AB-rated 20 mEq potassium chloride product,

as opposed to competition from other products. CPF 950-958.

The proposed finding is irrelevant because in this case, it is unnecessary to define the relevant market, one can directly assess that Schering had market power with K-Dur 20 by examining the control that Schering exercised over the price over time. Schering marketing documents show that Schering was able to increase sales of K-Dur 20, before September 2001, despite pricing it at a substantial premium to generic potassium chloride products. CPRF 3.38.

3.40. Schering's K-Dur 20 was competing in a crowded market that consisted of all oral potassium chloride supplements. (15 Tr. 3412 (Russo)). Schering believed it was competing against every potassium chloride product in the market. (*Id.* at 3411). Schering did not perceive that K-Dur 20 offered any significant therapeutic advantages over other potassium chloride products. (24 Tr. 5692-93, 5696 (Addanki); SPX 1111).

Complaint Counsel's Response to Proposed Finding 3.40:

The proposed finding is contradicted by other evidence. As shown in its own marketing documents, Schering was well aware of the therapeutic advantages K-Dur 20 offered over other potassium chloride products. CX 2 at SP 003043 (K-Dur 20 mEq Review) (stating greater patient compliance and safety with K-Dur 20); CX 1549 at 30:15-19 (DiLascia dep.) (20 mEq dose was sufficient for prophylaxis against hypokalemia); *See also* CPF 1046-1070. In fact, Schering stressed its therapeutic advantages in its promotion of K-Dur 20. Tr. at 25:6020-21, 25:6023 (Addanki).

3.41. A 1996 Schering marketing backgrounder states that "K-Dur competes in a crowded $264 million potassium market which continues to grow. . . ." (15 Tr. 3412 (Russo)) (CX 17, CX 746) (4 Tr. 720-21 (Bresnahan)). The marketing backgrounder was created by Schering's marketing research department in connection with the preparation of Schering's marketing plan. (15 Tr. 3412 (Russo).

Complaint Counsel's Response to Proposed Finding 3.41:

The proposed finding is misleading. *See* CPRF 3.39. Also, both of the Schering internal documents cited state clearly that the generic potassium chloride products mainly gain market share from the 8 and 10 mEq products. CX 17 at SP 003941 (K-Dur Marketing Research Backgrounder); CX 746 at SP 23 00370 (same document).

3.42. In 1996, 1997 and 1998, the potassium chloride supplement market was "very crowded" and "competitive." (*Id.* at 3412-13).

Complaint Counsel's Response to Proposed Finding 3.42:

The proposed finding is irrelevant. *See* CPRF 3.39-41.

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

Complaint Counsel's Response to Proposed Finding 3.43:

The proposed finding is irrelevant. *See* CPRF 3.39-41.

3.44. Schering perceived that K-Dur's major competitors were Klor Con and generic

potassium chloride. (CX 20) (5 Tr. 827 (Bresnahan)). A number of Schering documents characterize generic 10 mEq forms of potassium chloride as Schering's "major competitors." (6 Tr. 1170 (Bresnahan)). Schering's documents refer to the 8 mEq and 10 mEq versions of Klor Con as major competitors for K-Dur. (*Id.* at 1171).

Complaint Counsel's Response to Proposed Finding 3.44:

The proposed finding is irrelevant. *See* CPRF 3.39-41.

3.45. There are no Schering documents that support the notion that K-Dur 20 did not compete with generics, with other brands, with liquids, or with powders. (24 Tr. 5710 (Addanki)). Professor Bresnahan acknowledged that Schering's documents regarded the "total market" for K Dur 20 as all potassium chloride supplements. (3 Tr. 437 (Bresnahan)) (CX 133).

Complaint Counsel's Response to Proposed Finding 3.45:

The proposed finding is irrelevant and misleading. *See* CPRF 3.39-41.

3.46. Based on this evidence, Dr. Addanki concluded that Schering viewed the marketplace in which K-Dur competed as a crowded market, which included lower dose and lower cost generic products. (24 Tr. 5708 (Addanki) (SPX 977 at SP 003846) 5708).

Complaint Counsel's Response to Proposed Finding 3.46:

The proposed finding is irrelevant and misleading. *See* CPRF 3.39-41.

f. Upsher-Smith viewed its potassium chloride products as competing in the same market as K-Dur 20

3.47. Upsher-Smith believed it was competing against everyone selling potassium chloride, including K-Tab, Micro-K, Ethex, K-Dur, and Slow K. (24 Tr. 5711 (Addanki)) (SPX 1050). Upsher focused on the entire potassium chloride market and did not differentiate between dosage strengths. (20 Tr. 4692 (Dritsas)).

Complaint Counsels Response to Proposed Finding 3.47:

The proposed finding is irrelevant and contradicted by other evidence. *See* CPRF 3.39. Upsher did focus its marketing attention, as it relates to producing its own 20 mEq product, on K-Dur 20. *See* CPF 962; CPF 964-968; CX 21 at USL12832 ("Since K-Dur 20 is currently the only 20 mEq SR tablet on the market, the market represents a great opportunity for USL."). This finding is a clear example of the "cellophane trap." It is common for a monopolist to set its price so high that some substitution with other products may occur, however, that does not mean that the relevant market is competitive. CPF 1086-1089. A monopolist may in fact "raise its price sufficiently above competitive levels so that it eventually faces some competition from other products." Tr. at 34:8012-13 (Bresnahan); CPF 1089. Therefore, this finding is irrelevant because if Upsher-Smith's Klor Con M10 was substituted for K-Dur 20 in some cases, that is in keeping with the consequences of a monopolist's pricing behavior. It should be noted that despite K-Dur 20's supracompetitive prices, substitution was still exceedingly rare, especially in relation to other potassium chloride products, (*See* CPRF 3.60), and K-Dur 20 still enjoyed a high and increasing portion of sales of potassium chloride products:

Share of Total Dollar Sales
All Potassium Chloride Products:

Product	% share-1995	% share-1996	% share-1997	% share-1998	% share-1999	% share-2000
K-Dur 20	46.2%	52.2%	58.3%	63.0%	64.0%	66.8%
K-Dur 10	4.2%	4.7%	5.2%	5.6%	5.8%	6.3%
Total K-Dur	50.4%	57.0%	63.4%	68.6%	69.9%	73.2%
Total Upsher-Smith Klor-Con	6.9%	6.8%	6.5%	6.2%	5.5%	4.5%
Total Potassium chloride supplements	100%	**100%**	**100%**	**100%**	**100%**	**100%**

Source: CPF 1073.

3.48. Upsher's documents indicate that it was looking at the entire potassium chloride market in positioning its Klor Con 10 potassium chloride product. (20 Tr. 4692 (Dristas)) (24 Tr. 5711 (Addanki)).

Complaint Counsel's Response to Proposed Finding 3.48:

The proposed finding is irrelevant. *See* CPRF 3.47.

3.49. Upsher's training manuals throughout the 1990's noted that liquids, effervescent tablets, and sustained-release tablets are equally effective in replacing potassium and minimizing side effects. (21 Tr. 4950-51 (Freese)) (20 Tr. 4779 (Dritsas)) (USX 410 at Upsher-Smith FTC-190291).

Complaint Counsel's Response to Proposed Finding 3.49:

The proposed finding is irrelevant and misleading. *See* CPRF 3.47-48. It should be noted that Upsher recognized that the market was trending towards tablets and capsules to the point that data regarding liquids, powders, and effervescent tablets was not

even included in Upsher marketing data relating to potassium chloride. CX 1493 at 43:11-44:25 (Dolan Dep). Liquids and powders were know to have a terrible taste and after taste, (CX 2 at SP 0034043 (K-Dur 20 mEq Review)), this among other negative characteristics made them largely unpreferable to solid dosage forms of potassium chloride supplements. CPF 1043-1047. Even an Upsher-Smith training manual notes that the K-Dur and other pill forms mask the unpalatable taste of potassium chloride, (USX 410 at Upsher-Smith FTC 190291 (Klor Con Training Manual)), which in turn helps to get patients to take and stay on that medication. *See* Tr. at 2:208 (Teagarden).

3.50. In its 1996 market share projections, Upsher assumed that the potassium market, which included K-Dur 10, K-Dur 20 and all other potassium products, was a $218 million market. (20 Tr. 4700 (Dritsas)) (USX 1549 at USL 13858).

Complaint Counsel's Response to Proposed Finding 3.50:

The proposed finding is irrelevant. *See* CPRF 3.47.

3.51. 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. (20 Tr. 4691-92, 4696 (Dritsas); USX 1549 at USL 13858).

Complaint Counsel's Response to Proposed Finding 3.51:

The proposed finding is irrelevant. *See* CPRF 3.47.

3.52. In June 1997, Upsher-Smith viewed the potassium market as including a number

of potassium chloride products. (20 Tr. 4663 (Dritsas)). There were multiple competitors, all with different types of promotional and pricing strategies. (*Id.*). The market was crowded with very different competitors. (*Id.*).

Complaint Counsel's Response to Proposed Finding 3.52:

The proposed finding is irrelevant. *See* CPRF 3.47.

3.53. An Upsher 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. (20 Tr. 4738-39 (Dritsas); 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 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 4739) (USX 630 at USL 15333). K-Lor powder is marketed by Abbott Laboratories, a major, multi-billion dollar pharmaceutical company. (Dritsas 4739-40). Finally, at least two effervescent tablet products were in the potassium market, Klor Con/EF and K-Lyte. (Dritsas 4740) (USX 630 at USL 15333).

Complaint Counsel's Response to Proposed Finding 3.53:

The proposed finding is irrelevant. *See* CPRF 3.47; CPRF 3.49.

3.54. The 2000 training Upsher-Smith manual groups potassium chloride, potassium gluconate, potassium chloride bicarbonate, and potassium acetate together as competing for the

sale of potassium. (20 Tr. 4780(Dritsas) (USX 410 at Upsher-Smith FTC-190292)).

Complaint Counsel's Response to Proposed Finding 3.54:

The proposed finding is irrelevant. *See* CPRF 3.47.

3.55. In 2000, Upsher compiled a list of companies that compete with products in the potassium market, including Schering/Key, Ethex, Upsher and Ther-Rx. (20 Tr. 4800 (Dritsas) (USX 822)).

Complaint Counsel's Response to Finding No. 3.55:

Complaint counsel has no specific response.

3.56. Upsher was particularly aware of the substitutability between 10 mEq products and 20mEq products. (CX 190 at Upsher-Smith at FTC 138947).

Complaint Counsel's Response to Proposed Finding 3.56:

The proposed finding is irrelevant and misleading. The empirical data shows that before a generic 20 mEq product was launched, K-Dur 20 had an unusually low substitution rate. *See* 3.60. Furthermore, before a generic was launched, K-Dur 20 could still be set at supracompetitive prices and gain a large share of sales of potassium chloride products in the face of generic versions of other potassium chloride products, such as Klor Con 10, that were sold at substantial premiums. *See* CPRF 3.37; CPRF 3.47; *see also* CPRF 3.66; CPRF 3.67. And Upsher was well aware that the only significant competitive threat that could be posed to K-Dur 20, was a generic 20 mEq product. CX 1490 at 60:21-61:4 (Coleman dep.); *see also* CPF 964 - 968 (Upsher forecasts appreciated

the opportunity the 20 mEq market would present to a lower-priced generic 20 mEq competitor).

3.57. Upsher's marketing documents reflect the fact that K-Dur 20 "competes directly against the 8 and 10 mEq strengths" of Upsher's Klor Con. (5 Tr. 845 (Bresnahan); 20 Tr. 4689, 4696 (Dritsas) 4696, Dritsas 4689) (CX 740).

Complaint Counsel's Response to Proposed Finding 3.57:

The proposed finding is irrelevant and misleading. *See* CPRF 3.47; CPRF 3.60.

3.58. In 1996, Upsher viewed the "10/20 mEq Tablet Market" as becoming "increasingly competitive." (20 Tr. 4695-96 (Dritsas) (USX 1549)).

Complaint Counsel's Response to Proposed Finding 3.58:

The proposed finding is irrelevant. *See* CPRF 3.47.

3.59. Upsher was worried that if another company entered with an AB-rated generic version of K-Dur 10, demand for 20 mEq tablets would "collapse" before Upsher could introduce Klor-Con M20. (CX 190 at Upsher-Smith at FTC 138947).

Complaint Counsel's Response to Proposed Finding 3.59:

This finding is irrelevant because at the time of the settlement there was no generic K-Dur 10 available and there were not even any filed ANDA's signaling anyone's intent to enter the market with an AB rated generic version of K-Dur 10. Upsher's speculations on the impact of a generic K-Dur 10 product in the absence of a generic K-

Dur 20 does do not alter the facts that 1) Schering was able to raise the price of K-Dur 20 without losing sales (CPF 972-987); 2) generic K-Dur 20 was forecasted, and did take, substantial sales from K-Dur 20 at a substantial discount (CPF 952-971, 988-992); 3) only generic K-Dur 20 was forecasted, and did, force Schering to lower the price of its 20 mEq potassium supplement by launching its own generic K-Dur 20 (CPF 993-1036)

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

(1) Managed care and other buyers drove competition between Schering's K-Dur 20 and generics

3.60. Managed care organizations, purchasing groups and pharmacists made the majority of decisions on which potassium products would be dispensed. (20 Tr. 4751-52 (Dritsas) (USX 498 at USL 06872)). Schering was forced to compete to hold onto business as a result of the competitive pressures in the generic market. (20 Tr. 4843 (Dritsas).

Complaint Counsel's Response to Finding No. 3.60:

The proposed finding is irrelevant and misleading. By state law, only physicians can decide if a prescribed drug can be substituted with a non-AB rated generic version. *See* CPF 34-36; CPF 1011-12. There was very little switching of prescriptions of K-Dur for other potassium chloride products as shown by the following data from IMS:

Percentage of Prescriptions Written for K-Dur 20 and Three Other Branded Potassium Chloride Products Which Were Filled by Another Potassium Chloride Product.

Product	1996	1997	1998	1999	2000
K-Dur 20	0.11%	0.10%	0.06%	0.06%	0.06%

Klor-Con 10	2.70%	2.90%	3.50%	4.10%	3.40%
Micro-K-10	71.9%	78.2%	82.2%	84.9%	87.2%
K-Tab	59.3%	64.9%	69.3%	74.4%	79.4%

Source: CPF 1001.

3.61. Potassium is one of the most commonly prescribed drugs on managed care organizations' formularies. (*Id.* at 4647-48). 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. (*Id.* at 4648).

Complaint Counsel's Response to Finding No. 3.61:

Complaint counsel has no specific response.

3.62. If the branded product is not on the managed care organization's formulary, a patient who wanted the branded product would have to pay the entire cost of the branded product. (*Id* at 4648-49). Alternatively, if both a generic and a branded product are on the managed care organization's formulary, the patient's co-pay might be lower for the generic. (*Id.* at 4648).

Complaint Counsel's Response to Finding No. 3.62:

Complaint counsel has no specific response.

3.63. As of March 1995, "several staff HMO models, including Kaiser, FHP, and PacifiCare [were] evaluating K-Dur's status versus the less expensive 10 mEq generics." (CX 13 at SP 003045);(4 Tr. 711 (Bresnahan)). Schering's documents reflect that "In the next few years, the IPA/PPO organizations will probably continue to reimburse for K-Dur 20, but some may

become more aggressive in reviewing/forcing physician prescribing behavior to dosing potassium 10 mEq BID, due to cost." (CX 13 at SP 003045).

Complaint Counsel's Response to Finding No. 3.63:

The proposed finding is irrelevant. *See* CPRF 3.60.

3.64. In part, managed care organizations were driving the competition by encouraging or even forcing participating physicians to use generic potassium chloride during the March 1995 time period. (4 Tr. 709, 713 (Bresnahan)). Indeed, there are several managed care organizations that will not reimburse patients for a 20 mEq product if there is a generically priced product on the market. (20 Tr. 4647 Dritsas).

Complaint Counsel's Response to Finding No. 3.64:

The first sentence of the proposed finding is not supported by the evidence cited. Professor Bresnahan did not affirmatively testify on the cited pages of the record that managed care organizations were actually driving the competition by encouraging or forcing participating physicians to use generic potassium chloride in March 1995.

The proposed finding is also irrelevant. *See* CPRF 3.60.

3.65. Merck-Medco was one of the managed care organizations that expected pharmacists participating in its formulary to remind their customers of alternatives when a non-formulary medication is requested. (3 Tr. 236 (Teagarden); (USX 126). Before late 2001, Merck-Medco did not list a 20 mEq potassium chloride product on its formulary. Teagarden 234; Teagarden 240-41; Teagarden 244; Teagarden 257; Teagarden 274; Teagarden 280) (USX

at Merck-Medco 000171; USX 127 at Merck-Medco 0179; USX 128 at Merck-Medco 000186; USX 690 at 26; CX 57 at Merck-Medco 000191).

Complaint Counsel's Response to Finding No. 3.65:

The proposed finding is incomplete and misleading. Mr. Teagarden later testified that K-Dur 20 was not listed on the formularies cited in the finding due to an unwitting mistake, (Tr. at 2:272 (Teagarden)), and that older formularies may not have listed different dosage forms separately. Tr. at 2:275-77 (Teagarden).

3.66. Merck-Medco can provide patients with sufficient potassium without including a 20 mEq product on its formulary, as a doctor can simply prescribe two doses of the 10 mEq strength of potassium chloride instead of prescribing a single-dose 20 mEq product. (3 Tr. 257-58 (Teagarden)).

Complaint Counsel's Response to Finding No. 3.66:

The proposed finding is not supported by the evidence. *See* CPRF 3.60. Also, the evidence shows that third party payers as well as patients and physicians, prior to September 2001, did not consider there to be any potassium chloride supplements to be substitutable with K-Dur 20. *See* CPF 1119-1123. In fact, Upsher's campaign targeted at physicians, to persuade physicians to prescribe two Klor-Con 10 tablets instead of one K-Dur 20 tablet failed as K-Dur 20's share of sales increased and Klor Con 10's share of sales was relatively flat. CPF 1024-1027.

3.67. In addition to managed health care providers, there were other institutional buyers

that forced competition among oral potassium chloride supplements. This included big buyers like WalMart. If a company like WalMart is dissatisfied with price terms and conditions, it knows how to exert the leverage needed to get better terms from and existing supplier or to go to another supplier. (25 Tr. 6180 (Addanki)).

Complaint Counsel's Response to Finding No. 3.67:

The proposed finding is contradicted by more reliable evidence. *See* CPRF 3.60; Institutional buyer Walgreens does not promote therapeutic substitution. CPF 1020-23 (excluded evidence).

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

3.68. Upsher built demand for its Klor Con potassium chloride products based on therapeutic substitution. (20 Tr. 4653 (Dritsas).

Complaint Counsel's Response to Finding No. 3.68:

The proposed finding is contradicted by other evidence, to the extent it suggests there was significant substitution of Klor Con products for K-Dur 20. *See* CPRF 3.37; CPRF 3.60. Since there were no generic products that were AB-rated to K-Dur 20, there was very limited substitution for K-Dur 20 as reflected in the charts listed in CPRF 3.37 and 3.60. This finding reflects the "cellophane fallacy" or "cellophane trap"; even if non-AB-rated generics were competing with K-Dur 20, one cannot infer from this that they were in the same economic market as K-Dur 20, or that K-Dur 20 did not have monopoly power in its own economic market. *See* CPRF 3.47. This is because even a monopolist

will seek to price in the elastic part of its demand curve, and with the price of the monopoly product at such supracompetitive levels, even products that are not good substitutes may be encouraged to compete. *See* CPF 1086-1089 (showing that respondents commit a fundamental error of economic analysis – the "cellophane fallacy" – by arguing that the presence of competitors in the presence of monopoly pricing means that the alleged monopolist does not have market power).

This proposed finding is also misleading in that it implies a definition of the relevant market based on a marketing, rather than economic, meaning of the term. Defining the relevant economic market based on the use of the term market as defined in a marketing context by salespeople is vastly different from how it is used in the field of economics. CPF 1091; Tr. at 34:87053-54 (Bresnahan). This is not to say that there is no useful information in marketing documents; however, the term as defined in those documents should not be the primary basis for economic market definition. Even in its forecasts and marketing strategy Upsher recognized that the 20 mEq potassium chloride tablet market was distinct, and that its generic 20 mEq would be the first significant alternative to K-Dur 20. *See* CPF 962-968; CX 21 at USL12832 ("Klor-Con M20 is position to be the first quality, low cost alternative to K-Dur 20"); CX 1493 at 40: 18-41:22 (Dolan dep) (Upsher looked at K-Dur 20 as a separate market).

3.69. Klor Con 10 was therapeutically equivalent to K-Dur 20. (*Id.* at 4623). Two 10 mEq products could provide 20 mEq of potassium. (21 Tr. 4954 (Freese)). In order to compete against Schering's K-Dur 20, Upsher'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. (20 Tr. 4622-23 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.69:

The proposed finding is irrelevant. *See* CPRF 3.47; CPRF 3.60; CPRF 3.68. It should be also noted that Upsher's promotional campaign to convince physicians to substitute prescriptions for K-Dur 20 with two Klor Con 10 was an unsuccessful in shifting substantial sales from K-Dur 20 to Klor Con 10. CPF 1024-1028.

3.70. 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. (*Id.* at 4765-66) (USX 484 at USL 03330). Upsher trained its employees to tell doctors that rather than taking one K-Dur 20 tablet, a patient could take two Klor Con 10 tablets. (21 Tr. 4955-56 (Freese)). K-Dur 20 tablets are scored, making them easier to break in half. (21 Tr. 4955 (Freese)). 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. (20 Tr. 4622-23 (Dritsas)). Upsher's Klor Con 10 wax matrix tablet was about the same size as half a K-Dur 20 tablet. (*Id.* at 4624) (21 Tr. 4955 (Freese)). Klor Con 10 was easier to swallow, though, because a halved K-Dur 20 tablet was bulky with rough edges. (20 Tr. 4624 (Dritsas)). Klor Con 10 was round and aqueous coated, a good alternative for patients complaining about swallowing a big tablet. (Id. at 4624).

Complaint Counsel's Response to Finding No. 3.70:

The proposed finding is irrelevant. *See* CPRF 3.37; CPRF 3.60; CPRF 3.69.

3.71. Upsher was committed to targeting K-Dur 10 and K-Dur 20 pharmacy customers with its message of therapeutic substitution. (*Id.* at 4749-50). To determine which pharmacy customers to target, Upsher considered buying physician data revealing high prescribers of K-Dur at a price of $10,000. (*Id.* at 4750) (USX 498 at USL 06872).

Complaint Counsel's Response to Finding No. 3.71:

The proposed finding is irrelevant. *See* CPRF 3.37; CPRF 3.60; CPRF 3.69.

3.72. One marketing message used by Upsher was wax matrix's comparability to microencapsulated, extended-release products in terms of efficacy and safety. (*Id.* at 4778) (USX 410 at Upsher-Smith FTC-190275).

Complaint Counsel's Response to Finding No. 3.72:

The proposed finding is irrelevant. *See* CPRF 3.37; CPRF 3.60; CPRF 3.69.

3.73. Upsher 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. (20 Tr. 4754-56 (Dritsas); (USX 1551 at USL 13795). Upsher 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. (20 Tr. 4756-58 (Dritsas); (USX 1551 at USL 13795).

Complaint Counsel's Response to Finding No. 3.73:

The proposed finding is irrelevant. *See* CPRF 3.37; CPRF 3.60; CPRF 3.69.

3.74. Upsher emphasized both quality and low cost, identifying K-Tab, Klotrix, K-Dur 10 and K-Dur 20 as its major competitors. (20 Tr. 4698 (Dritsas); (USX 1549 at USL 13858). In 1997, Upsher began using the tag line "The Economical K" with its Klor Con 10 product. (20 Tr. 4757-58 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.74:

The proposed finding is contradicted by other more reliable evidence, to the extent it suggests that Klor Con 10 and K-Dur 20 competed in the same economic market. *See* CPRF 3.60; CPRF 3.67. In fact, Upsher in its forecasts and marketing strategy recognized that the 20 mEq potassium chloride tablet market was distinct, and that its generic 20 mEq would be the first significant alternative to K-Dur 20. *See* CPF 962-968; CX 21 at USL12832 ("Klor-Con M20 is position to be the first quality, low cost alternative to K-Dur 20"); CX 1493 at 40: 18- 41:22 (Dolan dep) (Upsher look at K-Dur 20 as a separate market). Furthermore, this proposed finding is misleading in that it bases its definition of the relevant market on a marketing, rather than economic, meaning of the term. Defining the relevant economic market based on the use of the term market as defined in a marketing context by salespeople is vastly different from how it is used in the field of economics. CPF 1091; Tr. at 34:8053-54 (Bresnahan).

3.75. In mailings to high prescribers of K-Dur in 1997 and 1998, Upsher equated all potassium products in terms of therapy and then tried to distinguish its Klor Con 10 as the cheaper alternative. (*Id.*) (USX 480 at USL 03288). In these letters, Upsher made a direct price comparison between Klor Con 10 and K-Dur 20, stating that equivalent dosing of Klor Con 10

represented a "5 percent savings versus the leading brand of 20 mEq potassium tablets." (20 Tr. 4759-60 (Dritsas); (USX 480 at USL 03287)). K-Dur 20 was the leading brand. (20 Tr. 4760 (Dritsas)). The mailings also reminded physicians of the long-range cost of potassium therapy for patients who needed it for the rest of their lives. (*Id.* at 4761-62).

Complaint Counsel's Response to Finding No. 3.75:

The proposed finding is irrelevant. *See* CPRF 3.37; CPRF 3.60; CPRF 3.68; CPRF 3.69.

3.76. Direct mailings emphasized the quality of Klor Con and the 56 percent savings. (*Id.* at 4766) (USX 484 at USL 03328). These mailings continued through November 1999. (20 Tr. 4766-67 (Dritsas)) (USX 484 at USL 03331).

Complaint Counsel's Response to Finding No. 3.76:

The proposed finding is irrelevant. *See* CPRF 3.37; CPRF 3.60; CPRF 3.68; CPRF 3.69.

3.77. Select chains and mail order accounts also were targeted to implement a tactic designed to offer Klor Con 10 as a therapeutic alternative to more expensive and less profitable microencapsulated products, such as Ethex 10 and Micro-K 10. (20 Tr. 4766 (Dritsas) (USX 484).

Complaint Counsel's Response to Finding No. 3.77:

The proposed finding is irrelevant. *See* CPRF 3.37; CPRF 3.60; CPRF 3.68; CPRF 3.69.

3.78. Upsher also tried to convince managed care organizations to list Klor Con as preferred potassium products and/or asked that they consider not listing K-Dur at all. (20 Tr. 4699-700, 4704-05 Dritsas) (USX 1549 at USL 13869). Upsher talked to managed care organizations about the economic advantages of prescribing Klor Con powder, Klor Con effervescent tablets, Klor Con 8 mEq and Klor Con 10 mEq in an effort to persuade them to list its products on their preferred drug formularies. (20 Tr. 4647-48 (Dritsas)). If Klor-Con 10 is on the formulary, the physician could write a prescription for two Klor Con 10 tablets to ensure that the patient only has to pay the co-payment, or at least the smaller co-payment. (20 Tr. 4648-50 Dritsas)). For example, if Klor Con were listed on the preferred formulary, a patient's co-pay may be only $5, whereas K-Dur, if not listed on the formulary, would cost the patient $25. (*Id.* at 4705).

Complaint Counsel's Response to Finding No. 3.78:

The proposed finding is irrelevant. *See* CPRF 3.37; CPRF 3.60; CPRF 3.68; CPRF 3.69.

3.79. In 2000, Upsher redoubled its efforts to compete against the 20 mEq, increasing its promotion in the microencapsulated arena. (*Id.* at 4781).

Complaint Counsel's Respond to Finding No. 3.79:

The proposed finding is irrelevant. *See* CPRF 3.37; CPRF 3.60; CPRF 3.68; CPRF 3.69.

3.80. Upsher's 2000 training manuals focused on selling methods to draw market share

away from K-Dur 20 and included sample advertisements. (20 Tr. 4785-90, 4797-98 (Dritsas); (USX 410 at Upsher-Smith FTC-190347; USX 839). USX 1005, an advertisement, shows Upsher's continuing focus on convincing physicians that prescribing two Klor Con 10s instead of one K-Dur 20 is cheaper for patients and just as effective. (USX 1005) (20 Tr. 4795-97 (Dritsas)). Upsher was careful to note that the advertisement's cost comparison between Klor Con 10 and K-Dur 20 does not necessarily reflect actual cost to the patient. (*Id.* at 4796-97). Yet another advertisement conveyed the message that 2 Klor Con 10 wax matrix provided the same dose and same benefits as K-Dur 20, at a lower price, and might be easier to swallow because K-Dur 20 was a large pill. (*Id.* at 4622-23, 4796-97) (SPX 989); 20 Tr. 5712-14 (Addanki); (SPX 1053).

Complaint Counsel's Response to Finding No. 3.80:

The proposed finding, to the extent it asserts that Klor Con and K-Dur 20 were in the same product market, is contradicted by other more reliable empirical evidence of K-Dur 20's market performance and low incidence of generic substitution (*see* CPF 972-987) and evidence that payers, physicians, and patients did not regard other products as good substitutes for K-Dur 20. *See* CPF 1024-1070, 1119-23. Moreover, the proposed finding is irrelevant, in that the empirical evidence shows that Upsher's campaigns to substitute two Klor Con 10's for one K-Dur 20 was unsuccessful in shifting substantial sales to Klor Con from K-Dur 20. *See* CPRF 3.37; CPRF 3.60; CPRF 3.69. In addition, the fact that Upsher tried to use Klor Con 10 to compete with K-Dur 20 is irrelevant to whether the two products are in the same product market since, at monopoly price levels, even poor substitutes may appear attractive to some customers. *See* CPF 1086-1089

(explaining that respondents' market analyses commit the "cellophane fallacy"). Indeed, Upsher's attempt to compete with K-Dur 20 by means of Klor Con 10 is an example of how monopoly pricing will lure even products that normally would not be considered good substitutes to attempt to compete. CPF 1027.

(3) Schering competed against other potassium chloride products

3.81. Prescriptions of both Klor Con and generic potassium chloride were growing in the mid-1990s. (5 Tr. 823-24 (Bresnahan)) (CX 20). The share of total prescriptions of generic potassium chloride rose from 25 percent in 1994 to 30 percent in 1996. (CX 746 at SP 2300382). Similarly, total prescriptions of Klor Con 10 rose from 11 percent in 1994 to 12 percent in 1996. (*Id.*).

Complaint Counsel's Response to Finding No. 3.81:

The proposed finding is irrelevant. *See* CPRF 3.60; CPRF 3.67; CPRF 3.74.

3.82. This represented a trend in the market towards generic potassium chloride. (4 Tr. 732 (Bresnahan)). During the 1996 -1997 period, Klor Con 10 sales increased 33 percent, moving from 12 percent of total prescriptions to 16 percent. (5 Tr. 831 (Bresnahan)). Generic potassium chloride sales increased during the same period, moving from 29 percent to 30 percent of total prescriptions by 1997. (*Id.* at 832).

Complaint Counsel's Response to Finding No. 3.82:

The proposed finding is irrelevant. *See* CPRF 3.60; CPRF 3.67; CPRF 3.74.

3.83. This growth was coming at K-Dur 20's expense. (CX 746 at SP 23 00039) (4 Tr. 743-45, 477 (Bresnahan)) (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. (24 Tr. 5708, 5732-33 (Addanki)) (SPX 993 at SP 290039) (CX 20 at SP 004040).

Complaint Counsel's Response to Finding No. 3.83:

The finding is misleading and incomplete. Professor Bresnahan analyzed sales and determined that there was some limited substitution between K-Dur 20 and other potassium chloride products; however, that substitution was insufficient to constrain K-Dur 20's pricing. Tr. at 3:483 (Bresnahan). The fact that there was some substitution between K-Dur 20 and other potassium supplements is neither surprising nor probative: ""there will be some substitution for any product, whether it's a competitive product or a monopoly product." Tr. at 34:8011 (Bresnahan). Substitution is consistent with both a competitive and monopoly market. To draw an inference about the market place based solely on limited substitution is to fall into the Cellophane Fallacy. Tr. at 34:8010-11 (Bresnahan).

The proposed finding is also contrary to more reliable evidence. Empirical data clearly shows that before September 2001, K-Dur 20 increased in sales and prescriptions while its price was going up, and as the generic versions of other potassium chloride products enjoyed a substantial price advantage. *See* CPRF 3.37. The substitution rate of K-Dur 20 with other potassium chloride products was also exceedingly rare. *See* CPRF

3.60.

3.84. 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; (4 Tr. 717 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.84:

The proposed finding is irrelevant. *See* CPRF 3.60; CPRF 3.67; CPRF 3.74.

3.85. In 1995, Schering developed a marketing strategy to address competition from generic 10 mEq products. (CX 13 at SP 003046; 4 Tr. 715-16 (Bresnahan)). 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. (4 Tr. 714-715 (Bresnahan); CX 13 at SP 003044-48).

Complaint Counsel's Response to Finding No. 3.85:

The proposed finding is incomplete and misleading. *See* CPRF 3.60.

3.86. To accomplish this goal, Schering focused on educating physicians through its field force about the need for potassium supplementation and creating an association between the K-Dur brand name and good patient care. (15 Tr. 3421 (Russo)). Schering hoped that physicians

would remember the K-Dur name and prescribe it. (*Id.*). It was important to Schering that physicians wrote prescriptions specifically for K-Dur 10 or K-Dur 20, because if doctors simply prescribed potassium supplementation, pharmacists could switch the prescription to a generic potassium supplement. (*Id.* at 3418, 3420-21).

Complaint Counsel's Response to Finding No. 3.86:

The proposed finding is irrelevant. *See* CPRF 3.60; CPRF 3.67; CPRF 3.74; CPRF 3.85.

3.87. As of July 1996, Schering was aggressively marketing K-Dur to gain sales from generic potassium chloride products. (CX 718 at SP 23 00039) (4 Tr. 742 (Bresnahan)). 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); 4 Tr. 758 (Bresnahan); (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. (15 Tr. 3418-19 (Russo)).

Complaint Counsel's Response to Finding No. 3.87:

The proposed finding is irrelevant. *See* CPRF 3.60; CPRF 3.74.

The proposed finding is also misleading. Schering's promotional expenditures on K-Dur were relatively small and declining by the late 1990's. CPF 1124.

3.88. Schering was by far the leader in investments in the promotion and marketing of potassium chloride supplements. (*Id.* at 3426) (6 Tr. 1176 (Bresnahan)). Schering's promotional expenditures far exceeded those of Upsher-Smith and other generic manufacturers of generic

products. (4 Tr. 733 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.88:

The proposed finding is irrelevant. *See* CPRF 3.60; CPRF 3.74.

The proposed finding is also misleading. Schering's promotional expenditures on K-Dur were relatively small and declining by the late 1990's. CPF 1124.

3.89. Schering budgeted $9.5 million on marketing K-Dur in 1997. (15 Tr. 3425 (Russo)) (CX 18 at SP 23 00064). That figure does not include an additional approximately $10 million that Schering spent on field force resources. (15 Tr. 3425-26 (Russo)). Schering invested heavily in a field force of sales representatives that would be capable of educating physicians about potassium chloride products. (15 Tr. 3418-19 (Russo)).

Complaint Counsel's Response to Finding No. 3.89:

The proposed finding is irrelevant. *See* CPRF 3.60; CPRF 3.74.

The proposed finding is also misleading. Schering's promotional expenditures on K-Dur were relatively small and declining by the late 1990's. CPF 1124.

3.90. K-Dur 10 and 20 achieved their market share through effective marketing. (*Id.* at 3418). The rise in total prescriptions of K-Dur 20 from 27 percent of the potassium chloride supplement market in 1994 to 32 percent in April 1996 was accompanied by substantial promotional expenditures. (CX 746 at SP 23 00382) (4 Tr. 733 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.90:

The proposed finding is not supported by the evidence. *See* CPRF 3.60; CPRF

3.74. The document cited in the proposed finding actually states that promotional support for K-Dur declined 44% from 1994 to 1995, and 13% from 1995 as of the date the document was produced in 1996. CX 746 at SP 23 00372.

The proposed finding is also misleading. Schering's promotional expenditures on K-Dur were relatively small and declining by the late 1990's. CPF 1124.

3.91. Upsher-Smith recognized that Schering did a "good job" marketing potassium, although spending a great deal of money doing it. (23 Tr. 5621-22 (Troup)). With that kind of investment, it was not surprising to Upsher-Smith that Schering was able to increase its market share. (*Id.* at 5621-22).

Complaint Counsel's Response to Finding No. 3.91:

This proposed finding is irrelevant. *See* CPRF 3.74; CPRF 3.90.

The proposed finding is also misleading. Schering's promotional expenditures on K-Dur were relatively small and declining by the late 1990's. CPF 1124.

3.92. Consistent with Mr. Troup's observations, Schering's documents show that product familiarity and free samples, rather than any particular feature or benefit of the product itself, were the main reasons that physicians selected a particular potassium product. (SPX 1055) (24 Tr. 5700 (Addanki)). (*See also id.* at 5698).

Complaint Counsel's Response to Finding No. 3.92:

This proposed finding is contradicted by other evidence. *See* CPRF 3.67.

3.93. The potassium chloride market is particularly sensitive to promotion. (15 Tr. 3418 (Russo)). To reach its goal of $200 million in sales in 1997, Schering committed itself to increased promotional activities. (*Id.* at 3425) (CX 18).

Complaint Counsel's Response to Finding No. 3.93:

This proposed finding is not supported by the evidence. *See* CPRF 3.90.

3.94. Professor Bresnahan seems to place K-Dur 20 in its own product market based on Schering's efforts to promote K-Dur 20 as a brand, rather than on any actual product differences between K-Dur 20 and other potassium chloride products. (6 Tr. 1225-26 (Bresnahan)) (24 Tr. 5734 (Addanki)). But Professor Bresnahan conceded that Schering's investment in its 1997 marketing campaign was "to take customers from the generic 10 milliequivalent product." (4 Tr. 758-59 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.94:

The proposed finding is wrong, incomplete, and misleading. *See* CPRF 3.32; CPRF 3.60; CPRF 3.74; CPRF 3.84. This finding misstates Professor's Bresnahan's testimony. In fact, it was Schering's expert, Dr. Addanki, who defined the product market using marketing concepts rather then relying on actual economic and substitution data. CPF 1082; Tr. a 24: 5709-33 (Addanki); Tr. at 34:8008-10 (Bresnahan). Professor Bresnahan testified that the delineation of the product market should be based on the market position of the K-Dur 20, economic data, and that Schering's promotional efforts are irrelevant. Tr. at 6:1226 (Bresnahan).

h. The relevant product market consists of all oral potassium chloride supplements

3.95. All potassium chloride supplements are used for the same purpose and are therapeutically equivalent. (1 Tr. 144-45 (Goldberg)) (2 Tr. 232, 247-48, 250 (Teagarden)) (USX 123; USX 124; USX 125) (21 Tr. 4951-52 (Freese)) (20 Tr. 4655-56 (Dritsas)) (24 Tr. 5690 (Addanki)).

Complaint Counsel's Response to Finding No. 3.95:

The proposed finding is incomplete and misleading. Not all of the potassium chloride products are interchangeable or compete with each other directly. *See* CPRF 3.13; CPRF 3.28; CPRF 3.29; CPRF 3.60.

3.96. Physicians viewed K-Dur 20 as a product for which there were numerous other alternatives. (20 Tr. 4834 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.96:

The proposed finding is not supported by the evidence. There is no evidence of substitution of non-AB rated generics for K-Dur 20 by physicians. *See* CPF 1024-1028.

3.97. Dr. Addanki looked at the cross-elasticity of demand between Schering's products and the other products in the market. (24 Tr. 5716 (Addanki)). In 1997, the demand for K-Dur 20 was elastic and there was sufficient cross-elasticity with other potassium chloride supplements that were all in the same product market. (24 Tr. 5716 (Addanki)).

Complaint Counsel's Response to Finding No. 3.97:

The proposed finding is contradicted by other evidence. Throughout the late 1990s, as K-Dur 20's prices increased, so did its share of sales and prescriptions. *See* CPRF 3.47: CPF 977-987.

3.98. Dr. Addanki also looked at whether there were side effect differences between different potassium chloride products that affected their substitutability for each other. (*Id.* at 5693). The primary side effect associated with potassium chloride products is the possibility of gastrointestinal (GI) irritation. (*Id.* at 5693-95). Gastrointestinal irritation is not a substantial problem, however, as its incidence is low for all oral potassium chloride supplements. (25 Tr. 6163 (Addanki)). Indeed, patients tolerate Klor Con 10 well. (20 Tr. 4662 (Dritsas)). K-Dur 20 does not eliminate this potential GI side effect. (24 Tr. 5693-95 (Addanki)). Thus, potential side effect issues do not affect the substitutability of other potassium chloride products for K-Dur 20. (*Id.* at 5695).

Complaint Counsel's Response to Finding No. 3.98:

The proposed finding is incomplete and contradicted by other evidence. K-Dur 20's microencapsulation technology reduces GI side effects, and that is one of K-Dur's therapeutic advantages that make it distinct from and more attractive than other potassium chloride products. *See* CPF 1049-1056.

3.99. Dr. Addanki also examined compliance issues to determine whether K-Dur 20 offered a material compliance advantage over other potassium chloride products. (*Id.* at 5695).

Complaint Counsel's Response to Finding No. 3.99:

The proposed finding is incomplete. *But see* CPF 1065-1067; CPRF 3.100; CPRF 3.103.

3.100. 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. (20 Tr. 4662 (Dritsas)). Upsher's sales brochures at this time referenced Klor-Con's clinical studies, which indicated a low incidence of adverse effects and low dropout rate, suggesting that the product was well-tolerated and well-accepted by patients. (*Id.* at 4776-77) (USX 410 at Upsher-Smith FTC-190347).

Compliant Counsel's Response to Finding No. 3.100:

The proposed finding is contradicted by other evidence. In his testimony, Mr. Dritsas admits that he is not aware of any comparative studies or research that has been done in the area of patient compliance concerning K-Dur that would support his assertion. Tr. at 20:4662 (Dritsas). In fact, Upsher's own expert witness and Schering's internal documents support the opposing assertion that K-Dur 20 increases patient compliance. Tr. at 27:6562 (Kerr) ("[T]he use of K-Dur 20 increases patient compliance compared to earlier products."); CPF 1065-1067.

3.101. Dr. Addanki found that Schering's own documents suggest that K-Dur had certain disadvantages. (24 Tr. 5696 (Addanki)) (SPX 1111). One of the most common reasons patients switched from K-Dur 20 to another product was GI upset, cost, and tablet size. (SPX 1111 at SP 004065, 004077); (24 Tr. 5697 (Addanki)).

Complaint Counsel's Response to Finding No. 3.101:

The proposed finding is incomplete. First, only 6% of the patients that started K-Dur 20 therapy switched to another product in the 12 months to which the study refers. Second, one quarter of the patients who discontinue K-Dur 20 therapy or switch to another product reinitiate K-Dur therapy in a later month. SPX 1111 at SP 004065.

3.102. K-Dur 20 was a big pill whose size made it difficult to swallow. (SPX 1111) (24 Tr. 5697 (Addanki)). The large size of the tablet is a marketing disadvantage and creates a "real challenge" when Schering promotes it to physicians, who in turn have to educate their patients. (15 Tr. 3422 (Russo)). Each K-Dur 20 tablet has a scoring, which is a line in the middle of the tablet that allows that patient to split it in half. (*Id.* at 3422-23). Splitting the pill in half makes the tablet easier to swallow or mix in liquid. (*Id.* at 3423). It also turns the 20 mEq pill into two 10 mEq pills.

Complaint Counsel's Response to Finding No. 3.102:

The proposed finding is incomplete. K-Dur 20 has the ability to retain sustained release characteristics even when the tablet is broken in half or dissolved in water. SPF 3.407; CPF 1063; Tr. at 13:2957 (Banker). This allows it dosing flexibility. CPF 1062-64. In part because of this flexibility, the rate of switching was still very low. CPF 1001. Also, Upsher promotions to switch from K-Dur 20 to more frequent dosing of Klor Con 10 were not successful. CPF 1025-27.

3.103. Upsher did not view K-Dur 20 as having compliance advantages: "There appears

to be no particular clinical advantage of one strength over another. However, the size of 20 mEq tablets presents swallowing issues for some patients." (USX 393 FTC 152061 at Upsher-Smith). Wax matrix tablets could be smaller and easier to swallow than the microencapsulated products. (Dritsas 4778) (USX 410 at Upsher-Smith FTC 190302).

Complaint Counsel's Response to Finding No. 3.103:

This finding is contradicted by other evidence. Upsher executives were aware of the compliance advantages of K-Dur 20. USX 410 at Upsher-Smith FTC 190291 (Klor Con Training Manual); CX 1496 at 40:9-13 (Dristas dep) ("[I]f you can swallow it whole rather than taking two tablets, you could take one and some people are absolutely willing to pay more for that convenience."); CX 1493 at 29:25-31:3 (Dolan dep).

3.104. Professor Bresnahan acknowledged that there were compliance problems with K-Dur, including that some patients found the pill hard to swallow, some experienced stomach irritation, some had the tendency to view a potassium supplement as a vitamin, and others experience side effects such as general intestinal upset or nausea. (4 Tr. 725-29 (Bresnahan)). A Schering marketing document from September 1996 states that "low patient compliance/persistency remains the most important issue for 1997." (CX 18 at SP 23 00039; 4 Tr. 742-43(Bresnahan)). Elsewhere in the same document, Schering cites findings from several studies on K-Dur 20, which found that 78 percent of all patients ceased persistent use of the product within a 12 month period. (CX 18 at SP 23 00046).

Complaint Counsel's Response to Finding No. 3.104:

The proposed finding is misleading and incomplete. Although K-Dur 20 was not

perfect, it substantially increased the likelihood of patient compliance as compared with other potassium chloride products. *See* CPRF 3.100; CPRF 3.103; CPF 1065-1067.

3.105. Professor Bresnahan is unaware of clinical trials that compare patient compliance attributes of taking two 10 mEq tablets versus one 20 mEq tablet. (4 Tr. 692 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.105:

The proposed finding is misleading in that it suggests the existence of clinical trials of which Professor Bresnahan was ignorant, when in fact counsel for Upsher acknowledged that no such trials existed. Tr. at 4:692 (Bresnahan). The proposed finding is otherwise irrelevant. *See* CPF 1065-1067; CPRF 3.100; CPRF 3.103.

3.106. K-Dur 20's 20 mEq dosage gives K-Dur a slight marketing advantage. (15 Tr. 3422 (Russo)). Schering tried to differentiate K-Dur 20 from other potassium chloride products by promoting it as the only once-daily 20 mEq potassium supplement on the market at the time. (*Id.* at 3469-70) (CX 18). Schering marketed the drug as more versatile than the other potassium products, advertising that patients could break it in half and take as two 10 mEq halves, or dissolve it in water. (15 Tr. 3470 (Russo)). Stressing this flexibility in dosing, Schering even marketed "cool little straws" that allowed patients to take K-Dur 20 as a liquid. (*Id.* at 3470 (Russo)).

Complaint Counsel's Response to Finding No. 3.106:

The proposed finding is irrelevant. *See also* CPF 1062-1064 (K-Dur 20 is further distinguished by its flexibility in dosing options).

3.107. Schering's efforts to sell its oral potassium chloride supplements were not unusual in the pharmaceutical industry. Such advertising and promotion can be a very important dimension of competition. (25 Tr. 6207 (Addanki)) (USX 1090). "Marketing plays a very significant role" as an instrument of competition among rivals. (USX 1009) (5 Tr. 881 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.107:

Complaint counsel has no specific response.

3.108. It is well recognized that companies in the pharmaceutical industry try to position their products as unique, and that marketing and advertising messages are advocacy pieces that reflect this. (4 Tr. 682 (Bresnahan)). Thus, Schering ran a targeted mail program promoting K-Dur 20 as the only 20 mEq potassium supplement. (CX 746 at SP 2300054) (4 Tr. 759 (Bresnahan)). Such promotion did give Schering a slight marketing advantage. But the relevant product market is not defined by a firm's own product hype or puffing. (4 Tr. 681 (Bresnahan)). Rather, Schering's promotional efforts to distinguish its product from the many other potassium chloride supplements demonstrate that K-Dur 20 was not a product market all by itself.

Complaint Counsel's Response to Finding No. 3.108:

The proposed finding is contradicted by other evidence. Schering had monopoly power in the relevant market of 20 mEq tablets and capsules. Tr. at 3:420, 496 (Bresnahan); *see generally* CPF § XI.

3.109. Schering's marketing efforts led only to slight differentiation. Because of the

simplicity of producing potassium supplements and their broad availability to consumers, distinguishing one's product in the marketplace is difficult. (15 Tr. 3412-13 (Russo)). Decision-makers did not greatly distinguish between K-Dur 20 and other products. (24 Tr. 5692 (Addanki)). Accordingly, the potassium chloride market is largely undifferentiated, and all oral potassium chloride supplements are largely substitutable for one another. (15 Tr. 3412-13 (Russo)) (24 Tr. 5693 (Addanki)).

Complaint Counsel's Response to Finding No. 3.109:

The proposed finding is contradicted by more reliable evidence. Empirical data shows the exceedingly low rate of substitution for K-Dur 20 despite its substantial pricing premium over other potassium chloride products. *See* CPRF 3.18; CPRF 3.60; *see generally* CPF § XI.

3.110. The entire set of potassium chloride products that were taken orally were substitutes for one another and for K-Dur 20. (24 Tr. 5700-01 (Addanki)). The correct relevant product market in this case consists of all oral potassium chloride supplements. (*Id.* at 5683).

Complaint Counsel's Response to Finding No. 3.110:

The proposed finding is contradicted by more reliable evidence. Empirical data shows the exceedingly low rate of substitution for K-Dur 20 despite its substantial pricing premium over other potassium chloride products. *See* CPRF 3.18; CPRF 3.60.

2. Relevant Geographic Market

3.111. Professor Bresnahan did little more than assert there was a United States

geographic market. (3 Tr. 496 (Bresnahan)). He did so on the assumption that the relevant market consists only of 20 mEq tablets and capsules. (*Id.*). Assuming the relevant product market in fact consists of all oral potassium chloride supplements, Professor Bresnahan has not proposed any geographic market. Professor Bresnahan never even proposed a geographic market that would be justified if product market consisted of all oral potassium chloride supplements. Professor Bresnahan never testified as to how many foreign firms were able to sell oral potassium chloride supplements in the United States. He never testified as the level of imports. He never testified as to the level of overseas capacity that could be diverted to the United States in response to a small but significant price increase by United States suppliers of oral potassium chloride supplements.

Complaint Counsel's Response to Finding No. 3.111:

The proposed finding is incomplete and misleading. 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 (CPF 15-22). Schering had FDA approval to sell its K-Dur extended release potassium chloride tablets, and marketed those products, in the United States. Upsher also has FDA approval to sell its Klor-Con M extended release potassium chloride tablets, and markets those products, in the United States. CPF 163-165; *see also* CPF 1077-1080. K-Dur 20 was the only 20 mEq potassium chloride tablet or capsule sold in the United States prior to September 2001. *See, e.g.*, CX 16 at SP 003541 (K-Dur Marketing Research Backgrounder, July 1, 1996); Tr. at 15:3468-70 (R.Russo).

C. Schering Did not Have Monopoly Power with respect to K-Dur 20

3.112. Schering did not have monopoly power in the relevant product market. (24 Tr. 5824, 5942, 5820 (Addanki). At best, it had a relatively modest share of oral potassium chloride supplement sales. Moreover, entry in the oral potassium chloride supplement market is easy, and existing firms can expand rapidly. Schering therefore did not exercise monopoly power with respect to K-Dur 20. (24 Tr. 5824, 5942, 5820 (Addanki)).

Complaint Counsel's Response to Finding No. 3.112:

Proposed Findings No. 3.112 through 3.137 are irrelevant, to the extent they assert, and rely on the assertion, that the relevant product market is something other than 20 mEq potassium chloride tablets and capsules – *i.e.,* K-Dur 20 and its AB-rated generic equivalents. *See generally* CPF 932-1128 (relevant market defined).

Proposed Findings No. 3.112 through 3.137 also are misleading and not supported by the evidence, to the extent that they suggest that potassium chloride products other than generics that were AB-rated to K-Dur 20 competed in the same economic market with K-Dur 20. The evidence shows that non-AB-rated products did not constrain K-Dur 20's pricing, sales, or share of sales of all potassium chloride supplements, and that such products were rarely substituted for K-Dur 20, despite sizeable premiums in the price of K-Dur 20 over the prices of those products. *See* CPF 972-987, 997-1002 (showing that K-Dur 20's prices, sales, and share of sales increased annually, and that K-Dur 20's generic substitution rate was extremely low compared to other potassium chloride brands, despite the large effective discount relative to K-Dur 20 at which those generics were offered).

This proposed finding also is contradicted by other evidence. Schering had monopoly power in the relevant product market (*i.e.*, the 20 mEq potassium chloride tablet and capsule market). *See* CPF 932, 943-995 (Schering had market power). Moreover, impediments created by the Schering '743 patent, the FDA approval process, and state generic drug substitution laws meant that entry or expansion into the relevant market was difficult, and took many years. *See* CPRF 3.127-3.137.

1. Schering's Market Shares in the Relevant Market

3.113. To ascertain whether Schering had monopoly power with respect to K-Dur 20, the market share of K-Dur 20 should be examined. (24 Tr. 5719 (Addanki)). A firm has a monopoly only if it is the only supplier of a product for which there is no close substitute. (34 Tr. 8139 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.113:

The second sentence of this proposed finding is misleading in its citation to Professor Bresnahan's testimony, in which he indicated that the textbook definition of "monopoly" is "not the same as an economist's definition of market power or monopoly power." Tr. at 34:8139-40 (Bresnahan). Professor Bresnahan later explained that a firm with monopoly power will increase the price, until products that are not good substitutes are able to be substituted at the margins. This does not mean that such a firm is not a monopolist and to so argue is to fall into the cellophane trap. Tr. at 34:8195, 8197 (Bresnahan) (explaining cellophane fallacy); CPF 1027, 1086-1089.

3.114. Complaint counsel cannot properly determine K-Dur 20's market share for two reasons. First, complaint counsel failed to establish the geographic market for oral potassium chloride supplements. Accordingly, complaint counsel cannot determine whether K-Dur 20 had monopoly power in a properly defined geographic market.

Complaint Counsel's Response to Finding No. 3.114:

This proposed finding is not supported by the evidence, which shows that the relevant geographic market is the United States. *See* CPRF 3.111.

3.115. Second, all of complaint counsel's prescription information comes from IMS data. IMS data fails to report sales by certain major chains such as Wal-Mart. (20 Tr. 4743-4744, 4675-4675, 4904-4905 (Dritsas)). The IMS data also tends to overstate the share of larger companies, typically. (28 Tr. 6918 (Kerr)).

Complaint Counsel's Response to Finding No. 3.115:

This proposed finding is incomplete and misleading. IMS data are the industry standard, and are widely used and relied upon by firms in the pharmaceutical industry and economic researchers. *See* Tr. at 3:471 (Bresnahan). Both Schering and Upsher purchase, utilize, and rely upon IMS data in their business planning. *See, e.g.*, CX 13 at SP 003044 (Memo re K-Dur long term strategy, March 8, 1995) (discussed at Tr. at 25:6015 (Addanki); CX 50 at USL 13474 (New Business Opportunities Klor-Con Tablets, April 1999) (discussed at Tr. at 25:6138 (Addanki)). Moreover, Dr. Addanki used IMS data during his direct testimony (Tr. at 24:5742, *see* 25:6189, 25:6203-04, 25:6199-200 (Addanki)), and acknowledged the accuracy of several conclusions drawn

from IMS data during his cross-examination. *See* Tr. at 25:5989-90, 25:6128-33 (Addanki). The respondents themselves rely on IMS data in their proposed findings. *See, e.g.*, Upsher Proposed Findings No. 48, 98-103, 203, 249, 253; Schering Proposed Findings No. 3.14, 3.169, 3.176, 3.201. In addition, Mr. Audibert relied on IMS data in making his evaluation of the Niacor-SR opportunity in June 1997. *See* Schering Proposed Findings No. 1.277-1.278.

With respect to the issue of Wal-Mart, IMS makes estimations as to data from Wal-Mart. CX 1496 at 61:14-21 (Dritsas dep). Those in the pharmaceutical industry consider IMS data reliable. CX 1496 at 61:14-21 (Dritsas dep) (testifying that, for evaluating and showing trends in the market, IMS data is generally reliable and is "the best source that's available").

3.116. Between 1994 and 2000, IMS data under-reported Upsher-Smith's actual sales. (CX 72 at USL 142534-535). For example, in 2000 IMS reported Upsher-Smith's unit sales at 309,841,000, while Upsher-Smith's actual unit sales were 487,393,000, or 57 percent more. The magnitude of the IMS under-report increased from 1995 (7 percent under-report) to 2000 (57 percent under-report).

Complaint Counsel's Response to Finding No. 3.116:

The proposed finding is not supported by the evidence. Both USL 142534 and 142535 of CX 72 list the source as IMS Data. The basis of this proposed finding is thus unclear. For the reliability of the IMS data, *see* CPRF 3.115.

3.117. Schering usually calculated K-Dur 20's market share on the basis of numbers of prescriptions, which is an appropriate way to perform these calculations. (34 Tr. 8133 (Bresnahan)) (CX 1766) (25 Tr. 6161-62 (Addanki)). When Schering calculated K-Dur's market share it included in the market all oral potassium chloride supplements. (CX 746 at SP 23 00382; Addanki 5720).

Complaint Counsel's Response to Finding No. 3.117:

This proposed finding is incomplete and misleading, to the extent it suggests that number and share of prescriptions are the only relevant statistics in considering market power. Share of revenues is an important indicator of K-Dur 20's market power, in that it provides evidence that other potassium chloride products were unable to restrain K-Dur 20's pricing. K-Dur 20's share of all potassium chloride revenues increased from 52.2 percent in 1996 to 66.8 percent in 2000 (approximately a 28 percent increase). *See* CPF 1073. During the same period, its unit share of all potassium chloride products increased from 32.6 to 37.6 percent of new prescriptions (a 15 percent increase), and from 30.9 to 36.3 percent of total prescriptions (a 17.5 percent increase). *See* CPF 1076; CX 62.

The Federal Trade Commission has long recognized that market shares should be calculated "using the best indicator of firms' future competitive significance. Dollar sales or shipments generally will be used if firms are distinguished primarily by differentiation of their products." DOJ/FTC, 1992 Horizontal Merger Guidelines § 1.41. The much higher share of sales revenues than unit sales is itself testimony to the fact that K-Dur 20 is a product differentiated from other potassium chlorides in several important ways. *See* CPF 1037-1070.

The fact that K-Dur 20's share of revenues could increase at nearly twice the rate of its share of unit sales, despite the availability of generic products priced one-half to two-thirds less, and that at the same time all other branded potassium chloride products were losing unit sales, revenues, and shares of unit sales and revenues to those generics (*see* CPF 977-983, 1076), is evidence of K-Dur 20's market power, in that it shows that the other generic and branded products did not constrain K-Dur 20's pricing to competitive levels.

3.118. Between 1995 and 1999, other Schering documents calculated the market share at between 30 and 40 percent. (6 Tr. 1169-70 (Bresnahan)). No Schering documents gave Schering a 100% market share.

Complaint Counsel's Response to Finding No. 3.118:

This proposed finding is incomplete and misleading. It is incomplete because Schering also examined K-Dur's share of total potassium chloride revenues. *See, e.g.*, CX 32 at SP 004099 (K-Dur Competitive Update). Moreover, numerous Upsher documents discuss a "20 mEq market" in which K-Dur 20 has a 100 percent share. *See, e.g.*, CX 30 at Upsher-Smith FTC 152964 (2000 Plan, Jan. 10, 2000) (The "20 mEq market" has "one player . . . K-Dur 20"); CX 50 at USL 13495 (New Business Opportunities Klor-Con Tablets, April 1999); CX 149 at USL06733; CX 150 at USL08538) (discussed at Tr. at 25:5987-88 (Addanki)).

It is misleading because between 1995 and 1999, Schering had the only 20 mEq potassium chloride tablet or capsule in the marketplace and had 100% of the relevant

market. *See, e.g.*, Tr. at 24:5900, 25:5965 (Addanki) (Prior to the entry of the AB-rated generic for K-Dur 20, Schering had 100 percent of 20 mEq potassium chloride tablet and capsule sales.); CX 50 at USL 13495 (New Business Opportunities Klor-Con Tablets, April 1999) ("K-Dur Market" with K-Dur 20 at 100% share). In overall potassium chloride sales, K-Dur 20's share of total dollar sales increased during this time from 46.2 percent in 1995 to 66.8 percent in 2000. CPF 1073; *see also* CPRF 3.112.

3.119. In March 1995, seventy-one percent of the potassium chloride prescriptions were for products other than K-Dur 20. (6 Tr. 1275 (Bresnahan) (CX 13 at SP 003044). In April 1996, sixty-eight percent of the potassium chloride prescriptions were for products other than K-Dur 20. (6 Tr. 1276-1277 (Bresnahan), (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).

Complaint Counsel's Response to Finding No. 3.119:

This proposed finding is irrelevant because the generic products on the market during this time period did not constrain the pricing of K-Dur 20. CPF 972-995. While the then available generic products were taking share from other potassium chloride products, they were not affecting K-Dur 20. *See* CX 16 at SP 003543 (K-Dur 20 was the

"only branded potassium chloride product with no AB-rated generic"); CPF 977-983, 1076 (while sales and shares of sales of K-Dur 20 and the non-AB-rated generics were increasing, sales and shares of sales of other branded potassium chloride supplements were declining). Almost no prescriptions written for K-Dur 20 were filled by another potassium chloride product during this period (CPF 1001; CX 43 (National Prescription Audit Data 1996-2000)), despite annual increases in the price of K-Dur 20, which is in sharp contrast to other branded potassium chloride products which had increasing substitution by generic products. CPF 1001; CX 43 (National Prescription Audit Data 1996-2000); *see also* CPRF 3.112.

3.120. Schering's documents show that, combined, Klor Con and the generics had a greater market share than K-Dur. (6 Tr. 1171 (Bresnahan)). CX 746 shows that as of April 1996, K-Dur 20 had a 37 percent market share of total prescriptions, compared with 30 percent for generic products, 9 percent for Micro-K, 15 percent for Klor Con, and 9 percent for other competitors. (CX 746 at SP 2300382).

Complaint Counsel's Response to Finding No. 3.120:

This proposed finding is irrelevant because the generic potassium chloride products on the market during this time period, including Klor Con, did not constrain the pricing of K-Dur 20. *See* CPF 972-995; CPRF 3.119; *see also* CPRF 3.112.

3.121. Schering documents note that generic potassium chloride has a higher market share than K-Dur 20. (6 Tr. 1171 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.121:

This proposed finding is irrelevant, incomplete and misleading. Numerous Upsher documents discuss a "20 mEq market" in which K-Dur 20 has a 100 percent share. *See, e.g.,* CX 30 at Upsher-Smith FTC 152964 (2000 Plan, Jan. 10, 2000) (The "20 mEq market" has "one player . . . K-Dur 20"); CX 50 at USL 13495 (New Business Opportunities Klor-Con Tablets, April 1999); CX 149 at USL06733; CX 150 at USL08538) (discussed at Tr. at 25:5987-88 (Addanki)).

It is irrelevant and misleading because the issue is whether the other potassium chloride products on the market could constrain the pricing of K-Dur 20, which they could not (CPF 972-995; CPRF 3.119), not whether other products sold more units than K-Dur 20. *See generally* CPF 932-1128.

3.122. In 1997, Schering had about a 30 percent market share of potassium prescriptions. (20 Tr. 4662-63 (Dritsas); 28 Tr. 6917 (Kerr)).

Complaint Counsel's Response to Finding No. 3.122:

This proposed finding is irrelevant and misleading. The issue is whether the other potassium chloride products on the market could constrain the pricing of K-Dur 20, which they could not (CPF 972-995; CPRF 3.119), not whether other products sold more units than K-Dur 20. *See generally* CPF 932-1128. Because the other products could not constrain the pricing of K-Dur 20, the relevant market is limited to 20 mEq tablets and capsules. Schering's share of overall potassium chloride prescriptions does not indicate whether Schering had market power in 20 mEq tablets and capsules. At all times up until

September 1, 2001, Schering had a 100% market share of 20 mEq potassium chloride tablets and capsules. *See, e.g.*, Tr. at 24:5900, 25:5965 (Addanki) (Prior to the entry of the AB-rated generic for K-Dur 20, Schering had 100 percent of 20 mEq potassium chloride tablet and capsule sales.); CX 50 at USL 13495 (New Business Opportunities Klor-Con Tablets, April 1999) ("K-Dur Market" with K-Dur 20 at 100% share); CPRF 3.118; *see also* CPRF 3.112.

3.123. 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).

Complaint Counsel's Response to Finding No. 3.123:

This proposed finding is irrelevant and misleading. *See* CPRF 3.122.

3.124. As of September 1996, Schering documents reflect that, together, K-Dur 10 and K-Dur 20 had a 37 percent market share of total prescriptions in the potassium chloride market. (CX 18 at SP 23 00370; 5 Tr. 814; CX 746 at 23 00382; Bresnahan)). Schering's 1997 Operating Plan for K-Dur includes market share data for both K-Dur 10 and 20. (CX 133). According to the 1997 K-Dur Marketing Plan, the actual market share of K-Dur 20 was actually less than 37 percent. (7 Tr. 1277 (Bresnahan)) (CX 18 at SP 23 00370; CX 746 at 23 00382).

Complaint Counsel's Response to Finding No. 3.124:

This proposed finding is irrelevant and misleading. *See* CPRF 3.122.

3.125. The 1998 K-Dur Marketing Plan also combines data for both K-Dur 10 and K-Dur 20. (CX 747) (7 Tr. 1279 (Bresnahan)). The market share for K-Dur 20 as of August 1997 was less than 38 percent. (7 Tr. 1279 (Bresnahan)) (CX 747 at SP 23 00091).

Complaint Counsel's Response to Finding No. 3.125:

This proposed finding is irrelevant and misleading. *See* CPRF 3.122.

3.126. Schering's market share does not indicate that Schering had monopoly power. (24 Tr. 5719, 5724 (Addanki); 25 Tr. 6209-10 Tr. 876 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.126:

The proposed finding is not supported by the evidence. Professor Bresnahan never testified that "Schering's market share does not indicate that Schering had monopoly power." The cited record only contains testimony that Professor Bresnahan did not see Schering documents containing market shares with certain percentages.

The proposed finding is also misleading. Professor Bresnahan testified that Schering's own calculation of market share neither proves nor disproves that it has monopoly power. "Market" as used by marketing people is irrelevant to an economic analysis of market definition or market power. Tr. at 34:8053-8054 (Bresnahan).

This proposed finding is also contradicted by other evidence. Schering had monopoly power in the relevant product market (*i.e.*, the 20 mEq potassium chloride tablet and capsule market), and had a 100% market share in that market until September 1, 2001. *See* CPF 932, 943-995 (Schering had market power); *see also* CPRF 3.112.

2. Lack of Entry Barriers

3.127. One also must examine ease of entry into the relevant market to determine whether a firm enjoys monopoly power. (24 Tr. 5720 (Addanki)). "Low barriers to entry into the market invite entry by new competitors and also expose firms well established in the market to the threat of potential entry. This in turn can induce those firms to hold prices, services, quality, and developments at competitive levels." (25 Tr. 6211-12 (Addanki). Thus, if entry is easy or barriers to entry are low, the exercise of market power or monopoly power could be thwarted. (25 Tr. 6210 (Addanki)).

Complaint Counsel's Response to Finding No.3.127.:

The proposed finding is irrelevant to the degree Dr. Addanki is commenting on the legal requirement for establishing market or monopoly power.

The proposed finding is also contrary to more reliable evidence. There is no one way to determine monopoly power or to define a market. Economist define markets to determine whether there is monopoly power: "Economist define markets in order to establish the area within which competition will decrease prices." Tr. at 6:1222 (Bresnahan). There are many methods used to define a market. An economist may directly assess entry and pricing effect on other products, an economist may use econometric data, surveys, or marketing data. There was direct evidence of the forecasted and actual impact of generic entry that established Schering's monopoly power. Carleton and Perloff also agree that there are many ways to define a market and assess market power: "Numerous methods are used to determine the good substitutes for a particular product." Tr. at 34:8129 (Bresnahan).

3.128. 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. (34 Tr. 8185 (Bresnahan)). Professor Bresnahan did not even analyze how long it took these firms to begin selling potassium chloride. (*Id.* at 8185-8186).

Complaint Counsel's Response to Finding No. 3.128:

This proposed finding is irrelevant, incomplete, and misleading. Professor Bresnahan testified that examination of entry conditions in the wider area of potassium chloride supplements generally was irrelevant, because the relevant product market is 20 mEq tablets and capsules. *See* Tr. at 34:8186.

3.129. In fact, entry barriers were low in the market for oral potassium chloride supplements. (20 Tr. 4725-26 (Dritsas); 24 Tr. 5722 (Addanki)).

Complaint Counsel's Response to Finding No. 3.129:

This proposed finding is contradicted by other evidence. There were several substantial impediments to entry into the market for 20 mEq potassium chloride tablet and capsules. First, any potential entrant had to invent around Schering's '743 patent, and either avoid or win any patent infringement lawsuits brought against them by Schering (or else wait until the patent expired in September 2006). *See* CPF 69-73. Second, a new entrant would have to undergo the FDA's ANDA approval process (*see* CPF 18-27), the length of which would depend, in part, on whether Schering filed a patent infringement suit and triggered a stay of up to 30 months on FDA's approval of the

pending ANDA. For example, Upsher filed its ANDA for Klor Con M in March 1995. Schering sued for patent infringement, and the parties settled on the eve of trial in June 1997 – over two years after the ANDA was filed, even without the time involved in conducting a trial. *See* CPF 85-87. Third, the record shows that, to be an effective competitor with K-Dur 20 in the relevant market, a generic would have to be AB-rated to K-Dur 20 by the FDA, because non-AB-rated generics were incapable of constraining K-Dur 20 competitively. *See* CPF 972-987, 997-1002 (showing that K-Dur 20's prices, sales, and share of sales increased annually, and that K-Dur 20's generic substitution rate was extremely low compared to other potassium chloride brands, despite the large effective discount relative to K-Dur 20 at which those generics were offered).

3.130. There were over 30 products competing as of 1997 in the potassium chloride market, all of which had entered at some point. (24 Tr. 5721-22 (Addanki)). A number of new competitors entered the market in recent years. (24 Tr. 5721 (Addanki); 20 Tr. 4715 (Dritsas)). Several companies entered the potassium chloride market in 1996, including Apothecon, ESI, Medeva and Biocraft, (*id.* at 4717 (Dritsas)) (USX 626 USL 15228). Apothecon in particular was a very low-priced competitor with a wide range of generic products, including 10 mEq potassium products a version. (20 Tr. 4717-18 (Dritsas)). 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 Upsher-Smith FTC-184403; (Addanki)).

Complaint Counsel's Response to Finding No. 3.130:

The proposed finding is irrelevant. None of the firms mentioned could constrain the

pricing of K-Dur 20. CPF 972-995; CPRF 3.119. Therefore, their presence is irrelevant. Tr. at 34:8185-86 (Bresnahan).

3.131. Ethex, one of the major competitors on the potassium market, did not even have a field force or a sales and marketing effort when it entered. (20 Tr. 4726 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.131:

Ethex did not produce a 20 mEq potassium chloride tablet or capsule. *See* Upsher Proposed Finding No. 66. Firms that did not produce 20 mEq tablets or capsules did not constrain the pricing of K-Dur 20. Therefore, the proposed finding is irrelevant. Tr. at 34:8185-86 (Bresnahan); CPRF 3.128, 3.130.

3.132. Ease of entry is also demonstrated by Upsher-Smith's introduction of an effervescent potassium chloride supplement. When Upsher wanted to introduce its Klor Con effervescent, it simply contacted a manufacturer, and Upsher "was on the market." (*Id.* at 4725-26).

Complaint Counsel's Response to Finding No. 3.132:

Effervescent potassium chloride supplements do not compete in the same relevant market with K-Dur 20. CPF 1043-1048. Therefore, the proposed finding is irrelevant. Tr. at 34:8185-86 (Bresnahan); CPRF 3.128. 3.130.

3.133. Thus, entry was not difficult.

Complaint Counsel's Response to Finding No. 3.133:

This proposed finding is contradicted by other evidence. There were several substantial impediments to entry into the market for 20 mEq potassium chloride tablet and capsules. *See* CPRF 3.129.

3. Ease of Expansion

3.134. If firms in the market can expand output with relative ease, Schering could not exercise monopoly power with respect to K-Dur 20. (24 Tr. 5720, 5721 (Addanki)).

Complaint Counsel's Response to Finding No. 3.134:

The proposed finding is irrelevant. Since Schering was the only firm in the relevant market, 20 mEq potassium chloride tablets and capsules, there were no other firms that could expand within that market. Moreover, the expansion of other potassium chloride producers who did not make 20 mEq potassium chloride tablets or capsules is irrelevant because such products did not constrain the pricing of K-Dur 20. CPRF 3.128, 3.130. This proposed finding also is contradicted by other evidence. There are several substantial impediments to entry or expansion into the market for 20 mEq potassium chloride tablet and capsules. *See* CPRF 3.129.

3.135. Firms already in the market could expand output. (24 Tr. 5722-23 (Addanki)). Apothecon's 10 mEq market grew 80 percent in 1998, which was a significant shift in sales of potassium chloride. (25 Tr. 6177 (Addanki)); CX 75 at USL 142364 and CX 73 at USL 143202-143203). 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 Upsher-Smith FTC-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 Upsher-Smith FTC-162109) (Addanki 6181) USL at 162109) (25 Tr. 6181 (Addanki)). Another product, Slow-K, showed a unit increase of 41% from 1994 to 1995. (25 Tr. 6181(Addanki) (USX 380. Market share moved in response to price. (25 Tr. 6182 (Addanki).

Complaint Counsel's Response to Finding No. 3.135:

The proposed finding is irrelevant. Since Schering was the only firm in the relevant market, 20 mEq potassium chloride tablets and capsules, there were no other firms that could expand within that market. Moreover, the expansion of other potassium chloride producers who did not make 20 mEq potassium chloride tablets or capsules is irrelevant, because such products did not constrain the pricing of K-Dur 20. CPRF 3.128, 3.130. This proposed finding also is contradicted by other evidence. There are several substantial impediments to entry or expansion into the market for 20 mEq potassium chloride tablet and capsules. *See* CPRF 3.129.

3.136. The weekly sales of a variety of oral potassium chloride supplements show that products may expand or contract output quite rapidly. (SPX 2282) (demonstrative) (24 Tr. 5723 (Addanki)). For example, Ethex 10 grew markedly from May 1997 through November 1999, while Kao Chlor lost share. (*Id.*) (SPX 2282) (demonstrative) (20 Tr. 4717 (Dritsas)). Klor Con 10 gained about 8 percent in sales in 2001. (25 Tr. 6200-01 (Addanki)) (CX 1480). Potassium chloride 10 and 20 mEq producers have been able to increase their sales by as much as 1,370.8

percent from one year to the next. (CX 75 at USL 142364; CX 73 USL at 143202-143203).

Complaint Counsel's Response to Finding No. 3.136:

The proposed finding is irrelevant. Since Schering was the only firm in the relevant market, 20 mEq potassium chloride tablets and capsules, there were no other firms that could expand within that market. Moreover, the expansion of other potassium chloride producers who did not make 20 mEq potassium chloride tablets or capsules is irrelevant, because such products did not constrain the pricing of K-Dur 20. CPRF 3.128, 3.130. This proposed finding is contradicted by other evidence. There are several substantial impediments to entry or expansion into the market for 20 mEq potassium chloride tablet and capsules. *See* CPRF 3.129.

3.137. The dramatic shifts in sales volume among firms indicate that firms can expand output relatively quickly. This is evidence that Schering did not have monopoly power. (24 Tr. 5724 (Addanki)).

Complaint Counsel's Response to Finding No. 3.137:

The proposed finding is irrelevant. Since Schering was the only firm in the relevant market, 20 mEq potassium chloride tablets and capsules, there were no other firms that could expand within that market. Moreover, the expansion of other potassium chloride producers who did not make 20 mEq potassium chloride tablets or capsules is irrelevant, because such products did not constrain the pricing of K-Dur 20. CPRF 3.128, 3.130.

This proposed finding also is contradicted by other evidence. There are several

substantial impediments to entry or expansion into the market for 20 mEq potassium chloride tablet and capsules. First, any potential entrant had to invent around Schering's '743 patent, and either avoid or win any patent infringement lawsuits brought against them by Schering (or else wait until the patent expired in September 2006). *See* CPF 69-73. Second, a new entrant would have to undergo the FDA's ANDA approval process (*see* CPF 18-27), the length of which would depend, in part, on whether Schering filed a patent infringement suit and triggered a stay of up to 30 months on FDA's approval of the pending ANDA. For example, Upsher filed its ANDA for Klor Con M in March 1995. Schering sued for patent infringement, and the parties settled on the eve of trial in June 1997 – over two years after the ANDA was filed, even without the time involved in conducting a trial. *See* CPF 85-87. Third, the record shows that, to be an effective competitor with K-Dur 20 in the relevant market, a generic would have to be AB-rated to K-Dur 20 by the FDA, because non-AB-rated generics were incapable of constraining K-Dur 20 competitively. *See* CPF 972-987, 997-1002 (showing that K-Dur 20's prices, sales, and share of sales increased annually, and that K-Dur 20's generic substitution rate was extremely low compared to other potassium chloride brands, despite the large effective discount relative to K-Dur 20 at which those generics were offered).

4. Sales of K-Dur were expanding

3.138. 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. (24 Tr. 5744 (Addanki)). Such activities have the effect of expanding output. (*Id.*). Dr. Addanki

analyzed Schering's output as part of his analysis of whether Schering had monopoly power. (*Id.*). Increasing sales is not a hallmark of monopoly. (25 Tr. 6159, 6171 (Addanki)). Rather, a monopolist wants to restrict output. (24 Tr. 5745 (Addanki)).

Complaint Counsel's Response to Finding No. 3.138:

An attempt to expand output is not evidence that a firm does not have monopoly power, since even a monopolist is to be expected to want to increase its unit sales, albeit through means other than price cutting. CPF 1124 (Schering's promotional activity does not mean K-Dur 20 did not have monopoly power). Increases in K-Dur 20 sales were not due exclusively, or even primarily, to Schering marketing and detailing. *See* Tr. at 25:6038-41 (Addanki) (acknowledging that K-Dur received only minimal promotional support from Schering). K-Dur's promotion-to-sales ratios on promotional spending (providing only "minimal detail and promotional support") were low by industry standards, and were declining during the late 1990s. CPF 1124 (Schering's promotional activity does not mean K-Dur 20 did not have monopoly power). K-Dur 20's commercial success rested, instead, primarily on: (1) the absence of a generic product AB-rated to K-Dur 20, which prevented automatic substitution of generics for K-Dur 20 at the pharmacy level (*see* CPF 996-1028); and (2) K-Dur 20's unique combination of physical characteristics, which greatly enhanced patient safety, convenience, and compliance (*see* CPF 1037-1070), and caused customers and physicians to view other potassium chloride supplements as poor substitutes for K-Dur 20. *See* CPF 1024-1036, 1069-1070, 1119-1123.

3.139. 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. (34 Tr. 8181 (Bresnahan)). According to Professor Bresnahan, between 1997 and 2001, K-Dur output increased by one-quarter (25 percent) from 800,000 TRX to 1,000,000 TRX. (34 Tr. 8181 (Bresnahan)).

Complaint Counsel's Response to Finding No.3.139:

Complaint counsel has no specific response.

3.140. Thus, Schering had an "output-enhancing role, not an output-shrinking role." (24 Tr. 5744 (Addanki)). That is the antithesis of how a monopolist behaves. (*Id.*).

Complaint Counsel's Response to Finding No. 3.140:

An attempt to expand output is not evidence that a firm does not have monopoly power, since even a monopolist is to be expected to want to increase its unit sales, albeit through means other than price cutting. CPF 1124 (Schering's promotional activity does not mean K-Dur 20 did not have monopoly power). Schering's increase in sales when it was raising prices (CPF 972-984) means that Schering had market power, not that it did not. *See* Tr. at 3:431-432, 3:475-476, 3:478-481, 3:483, 6:1227-1229 (Bresnahan).

D. Professor Bresnahan's Conclusion that Schering Had Monopoly Power Is Not Supported by the Evidence

1. Professor Bresnahan incorrectly defined the product market

3.141. Professor Bresnahan concedes that economists use a number of methodologies to

define markets, including measuring which products are particular close substitutes for other products, reviewing survey data of what people choose and what they would choose if competitive conditions changed, and relying on the content of marketing documents as the main carrier of the market definition. (6 Tr. 1224 (Bresnahan)). Professor Bresnahan used none of these methods.

Complaint Counsel's Response to Finding No. 3.141:

The finding is incomplete, misleading, and contradicted by other evidence to the extent that it indicates Professor Bresnahan did not examine the substitutability of other products, the behavior of potassium supplement consumers under the changing conditions of the marketplace in the relevant period of time, or used the content of marketing documents as carrying some information useful to defining the relevant market. The finding is contrary to more reliable evidence to the extent that it asserts the use of these methods are necessary to examining the economic relevant market.

Professor Bresnahan is an industrial organization economist. Tr. at 3:381; 3:407 (Schering counsel John Nields stating, "Dr. Bresnahan is clearly an expert in industrial organization economics."). Professor Bresnahan was retained to assess whether the settlement agreement between Upsher-Smith and Schering-Plough delayed generic entry and harmed competition. Tr. at 3:408 (Bresnahan).

Professor Bresnahan possesses all of the qualifications necessary to determine the amount and quality of information required in assessing the market definition. Dr. Bresnahan is a distinguished professor of economics at Stanford University. Tr. at 3:381 (Bresnahan); *See* CX 804 (curriculum vitae of Professor Bresnahan). He is a former chief

economist of the Antitrust Division at the Department of Justice. In that position, Professor Bresnahan worked on the economic analysis of Microsoft's monopoly power. Tr. at 3:388-91 (Bresnahan). Professor Bresnahan has edited several books. One such book, The Economics of New Goods, examined issues relating to new goods, including competition between new and existing goods. This book included the use of techniques which are relevant to this case. Tr. at 3:397-401 (Bresnahan). Professor Bresnahan has published over thirty articles in books and scholarly journals. Tr. at 3:402-403 (Bresnahan). The measurement of market power is the subject of many of these articles. Tr. at 3:403 (Bresnahan). Professor Bresnahan has pioneered tools used to assess market power, particularly in the context of antitrust matter. Tr. at 3:404 (Bresnahan).

Professor Bresnahan reviewed documents containing information on substitution and patterns of usage during the changing conditions of the marketplace. Professor Bresnahan reviewed marketing documents and relied on information contained within these documents. However, Professor Bresnahan expressly rejected the use of the word "market" by marketeers as relevant to a definition of the relevant economic market.

For example, Professor Bresnahan reviewed and testified about the 1997 K-Dur Marketing Plan, a document produced by Schering, which contains information on substitution and patterns of usage. CX 18; Tr. at 3:455-56 (Bresnahan). Professor Bresnahan reviewed the information in this document regarding possible substitution by physicians, pharmacists, and patients of K-Dur 20 with two 10 mEq tablets. CX 18 at SP 23 00049, 58, 63 ("1997 K-Dur Marketing Plan"). He also reviewed information in this document concerning managed care providers' patterns of usage. CX 18 at SP 23 00042-

44, 48-49. He reviewed the information in this document concerning patterns of usage by physicians, pharmacists, and hypokalemic patients. CX 18 at SP 23 00039, 43-47. He reviewed the information in this document concerning patterns of usage by pharmacy benefit managers, hospitals, federal agencies and state Medicaid plans. CX 18 at SP 23 00039, 42-44. He reviewed the information in this document concerning patterns and practices of drug wholesalers. CX 18 at SP 23 00039, 45.

Surveys are not the best evidence for examining the economic issues relevant to this case. Professor Bresnahan is aware of the use of surveys in connection with defining the relevant market. Professor Bresnahan considered the reliance on surveys to be a weaker methodology than the general economic literature on the effect of A-B rated generic entry, the direct evidence of what occurred when an A-B rated generic for K-Dur 20 entered the market, the assessments of market participants about the effect of entry by an A-B rated generic for K-Dur 20, and the market participants' explanations of the reason for this effect. Tr. at 6:1223-25 (Bresnahan).

Professor Bresnahan was aware of and did consider the physical characteristics of the K-Dur 20 tablet. Despite the physical characteristics and side-effects of K-Dur 20, Professor Bresnahan found little evidence of substitution by consumers. Tr. at 4:725-29 (Bresnahan) (testimony cited in the finding above). Professor Bresnahan concluded that the actual negative physical attributes and side-effects of K-Dur 20 were not significant because the negative physical attributes and side-effects did not lead consumers to substitute other products to the extent that the other products posed "significant competitive constraints" to K-Dur 20. Tr. at 3:432, 34:8038-8039 (Bresnahan).

Therefore, these negative physical attributes and side-effects "did't make it into [his] report ...". Tr. at 4:625 (Bresnahan) (Quoting Upsher counsel Mark Gidley).

Professor Bresnahan reviewed and addressed market share breakdown[s] from the files of firms sell potassium supplements. As a distinguished economist, Professor Bresnahan understands that in assessing the relevant market it is a mistake to rely on the word "market" as used by marketeers. Tr. at 34:8010-11 (Bresnahan) (explaining that the mistaken reliance by Addanki on these kind of documents led Addanki into the Cellophane fallacy). "I think -- I think that if you -- the very -- just the fact that it says that there's some competition, if you take that to mean they are necessarily in the market, then you've fallen into a cellophane trap." Tr. at 34:8195 (Bresnahan) (responding on cross-examination as to how an economist should properly utilize the information contained in marketing documents).

Professor Bresnahan did not seek additional documents because he was aware that "[e]ven a monopoly may raise its price sufficiently above competitive levels so that eventually it faces some competition from other products. Just because a monopolized product faces close demand substitutes at the monopoly price, it does not follow that the firm producing the product has no market power (though it may not be able to raise its price further)." Tr. at 34:8012 (Bresnahan) (agreeing with the quoted language from Carlton and Perloff); CX 1746 (demonstrative).

It is standard economics to disregard the use of the word market by marketing personnel. "Marketing people use the word "market" to mean a lot of different things. They don't necessarily use it to mean what an economist would mean by a "market." In

fact, that this -- this difference between what economists mean by "markets" and how marketing people in corporations use that word is sort of a fairly standard, recognized piece of economics, that you can't just rely on that word as a basis." Tr. at 34:8053-54 (Bresnahan). "The relevant economic market is not necessarily the same as the market that a salesperson might refer to. Substantial confusion has sometimes resulted when market definition is based on memos written by marketing personnel." Tr. at 34:8054 (Bresnahan) (agreeing with the quoted language from Carlton and Perloff); CX 1750 (demonstrative).

Statements by marketing personnel which suggest or define a market have little significance in determining the relevant economic market for antitrust purposes.

> Q. Professor, we've seen in the last two days quotes from documents in which Schering identified a potassium chloride market or identified generic 8 and 10 milliequivalent ones as competitors. Did you consider those statements in forming your opinion that Schering had monopoly power?
> A. Yes, I did.
> Q. What significance do those statements have?
> A. They have limited significance. Any -- let me say why in two ways. First off, it's a very well established piece of economics that any product has some substitutes and particularly if it's elevated its price, it's going to have some substitutes, so that there were some competitors. In the words of a marketeer, there are some products to which there's some limited substitution. That's always going to be true, so that -- so, the statement that they're there I think doesn't do very much.
>
> You know, and second, the -- the situation was one of -- with the absence of a generic for K-Dur 20. So, if you stand on K-Dur 20 before last September and ask what are the closest available substitutes, whether they're very important constraints or not, whether they're important constraints or not, they're going to have something other than a generic. So that when they looked out from there, under this very standard piece of economics, which there's always some substitution, what they're going to hit is something more -- more distant. So, that's why I put limited weight on those quotes.

Tr. at 6:1228-29 (Bresnahan).

3.142. Professor Bresnahan's definition of the relevant product market as 20 mEq tablets and capsules was incorrect. (25 Tr. 6186 (Addanki)) (CX 1596).

Complaint Counsel's Response to Finding No. 3.142:

The finding is contradicted by the evidence. *See* CPF 932-1128.

3.143. Professor Bresnahan defined the product market as a single-brand of potassium chloride and it's A-B related generic, based on the 20 mEq dosage size. (34 Tr. 8057 (Bresnahan)). Professor Bresnahan did not include any other dosage strengths of potassium chloride, such as two 10 mEq tablets. (*Id.*). Nor did Professor Bresnahan include any other forms of potassium chloride other than sustained release tablets and capsules. (34 Tr. 8057-58 (Bresnahan). Thus, Professor Bresnahan excluded liquid, powder, and effervescent tablet forms of potassium chloride. (34 Tr. 8057 (Bresnahan)). According to Professor Bresnahan, the *only* product in the relevant market during 1996 and 1997 was K-Dur 20. (4 Tr. 679-80 (Bresnahan)). And the only competitors to K-Dur 20 Professor Bresnahan recognizes between September and November 2001 are Upsher-Smith's Klor Con M20 and Warrick's generic version of K-Dur 20. (*Id.* at 649-50) (CX 1596).

Complaint Counsel's Response to Finding No. 3.143:

The finding is incomplete and misleading to the extent that the finding does not include information on the reasons Professor Bresnahan removed from the relevant market other dosage strengths and liquid, powder, and effervescent tablet forms of potassium chloride. *See* CPF 1037-1070.

Specifically, Professor Bresnahan found prior to September 2001, K-Dur 20's

unique physical characteristics – primarily its microencapsulation technology, its unique 20 mEq dosage strength, and its choice of several dosing options – differentiated it from other potassium chloride products with regard to patient safety, compliance, and convenience, and led customers to perceive that other potassium chloride products were not close substitutes for K-Dur 20. CPF 1043-1069. Liquid, powder, and effervescent tablet forms of potassium chloride supplements do not compete with K-Dur 20. CPF 1043-1048. K-Dur's unique microencapsulation process enhances patient safety by reducing the likelihood of gastrointestinal irritation or ulceration that can be caused by potassium chloride. CPF 1049-1056. K-Dur 20, as the only 20 mEq solid dosage potassium chloride product on the market prior to September 2001, enhanced patient convenience by allowing patients to reduce the number of pills they took, and by allowing many patients to reduce their number of daily dosages (in many cases, to a single daily dose). CPF 1057-1061. K-Dur 20 offers a wider and more flexible range of dosing options for patients than do other potassium chloride products. CPF 1062-1064. K-Dur 20 enhances the likelihood that patients will comply, and remain in compliance over time, with their doctors' prescribed potassium chloride therapy. CPF 1065-1068.

a. Professor Bresnahan ignored the substitutability of potassium chloride products

3.144. Professor Bresnahan conceded that two 10 mEq tablets are therapeutically interchangeable with one 20 mEq tablet. (6 Tr. 1173 (Bresnahan)). Professor Bresnahan conceded that 10 mEq tablets and 20 mEq tablets are not used for different purposes, and that

consumers can "reasonably take two 10 milliequivalent tablets in place of a 20 milliequivalent tablet." (*Id.*). Professor Bresnahan is not aware of any group of hypokalemic patients for whom potassium supplementation cannot be accomplished by either K-Dur 20 or by two Klor Con 10s. (4 Tr. 706-07 (Bresnahan). Professor Bresnahan even placed K-Dur 20 mEq tablets in a different product market from K-Dur 10 mEq tablets, even though K-Dur 10 is therapeutically equivalent to K-Dur 20. (*Id.*).

Complaint Counsel's Response to Finding No. 3.144:

The finding is incomplete and misleading to the extent that it fails to address Professor Bresnahan's reasoning for rejecting K-Dur 10 mEq and other 10 mEq formulations from the relevant economic market.

There is no evidence of significant switching away K-Dur 20 to 10 mEq products. *See* CPF 996-1036. Substitution of generic potassium chloride products for K-Dur 20 was minimal at either the pharmacist or physician level prior to September 2001. CPF 998-999, 1001-1003.

First, empirical data show that there was no significant substitution of generic drugs for K-Dur 20 prior to September 2001. *See* CPF 1001-1003. The empirical evidence indicates that, prior to September 2001, there was very little substitution, at either the physician or pharmacist level, of non-AB-rated products for K-Dur 20, despite the incentives of payers to control costs, and the price premium K-Dur 20 maintained over most other (particularly generic) potassium chloride products. *See* CPF 972-976, 1001-1002. Mr. Goldberg of United Healthcare testified that there were good reasons relating to patient compliance and convenience for discouraging the substitution of, for

example, two 10 mEq tablets for one K-Dur 20 mEq tablet, and that United Healthcare had never considered suggesting this to its participating physicians or patient members. Tr. at 1:169-70 (Goldberg).

Second, there was no AB-rated generic to K-Dur 20 in the market prior to September 2001; and state generic drug substitution laws did not permit the automatic substitution of a generic drug that is not AB-rated to K-Dur 20. *See* CPF 1004-1009. A primary reason why non-20 mEq potassium chloride supplements cannot control the pricing of K-Dur 20 is that pharmacists cannot automatically substitute other forms and dosages of potassium chloride for prescribed K-Dur 20. *See, e.g.,* Tr. at 3:484 (Bresnahan). If a pharmacist receives a prescription written for a K Dur 20 mEq tablet, he cannot simply substitute an 8 mEq or 10 mEq tablet without calling the physician. Tr. at 20:4845-46 (Dritsas). Similarly, if a prescription is written for a 20 mEq tablet, a pharmacist cannot substitute a potassium chloride powder, an effervescent tablet of potassium chloride, or a liquid potassium chloride without a physician's authorization. Tr. at 20:4846-4847 (Dritsas).

Third, the rate of therapeutic substitution of non-AB-rated generic drugs for K-Dur 20 is very low, because of the effects of state generic drug substitution laws and the higher switching costs attendant to substitution of non-AB-rated drugs, as opposed to AB-rated generic drugs, for a prescribed branded drug. *See* CPF 1004-1005, 1010-1013. "Therapeutic substitution involves filling a prescription with a drug that differs in chemical composition, dosage strength, and/or dosage form from the drug that the physician [has] prescribed." CX 1778 ¶ 11 (Declaration of William E. Groth, Divisional

Manager for Pharmaceutical Purchasing for Walgreen Co. ("Groth Declaration") – excluded evidence).

Ordinarily, prescriptions include the product or chemical entity, as well as the dosage form (*i.e.* tablets, capsules, liquid, or powder) and strength (*i.e.*, 20 mEq.). If a pharmacist wants to fill the prescription outside these parameters, then this is a therapeutic substitution and the pharmacist must receive physician approval. CX 1778 ¶ 7 (Groth Declaration- excluded evidence).

As Mr. Groth stated:

> Attempting [] therapeutic substitution is very time consuming. Therapeutic substitutions require a physician's attention on a case-by-case basis, and physicians generally will not consider a therapeutic substitution without talking directly with the pharmacist. It is often difficult to get physicians to the telephone, and pharmacists are often put on hold or told that they should call back at a later time. Once the pharmacist discusses the potential therapeutic substitution with the physician, it is far from certain that the physician will accede to the pharmacist's request. The time the pharmacist spends on the phone is time not spent filling prescriptions and meeting the needs of other customers. Thus, making a therapeutic substitution is costly to the pharmacist.

CX 1778 ¶ 13 (Groth Declaration- excluded evidence).

He stated that during the summer of 2001 there was a shortage of K-Dur 20. During that time, individual Walgreens pharmacists who were unable to obtain K-Dur 20 implemented therapeutic substitution with the physician's approval. If a generic formulation of potassium chloride 20 mEq had been available, the pharmacists would have filled those prescriptions with a generic equivalent instead of a therapeutic substitute. CX 1778 ¶ 16 (Groth Declaration - excluded evidence). According to Mr. Groth, Phillip Drilsas' testimony that Walgreens set a message in its system so that when

the prescription came up for K-Dur, the pharmacists were instructed to dispense two Klor Con 10 products, is erroneous. CX 1778 ¶ 8 (Groth Declaration- excluded evidence).

Therapeutic substitution of a non-AB-rated generic is less cost-efficient than automatic substitution of an AB-rated generic because of the attendant "switching costs." Tr. at 3:490-93 (Bresnahan). Mr. Goldberg of United Healthcare specifically rejected the notion of therapeutic substitution in the case of K-Dur 20, citing concerns that encouraging his plan's physicians or patients to substitute two 10 mEq tablets for one 20 mEq tablet would adversely affect patient compliance. Tr. at 1:169-70 (Goldberg).

K-Dur 20's unique physical characteristics – primarily its microencapsulation technology, its unique 20 mEq dosage strength, and its choice of several dosing options – differentiated it from other potassium chloride products with regard to patient safety, compliance, and convenience, and led customers to perceive that other potassium chloride products were not close substitutes for K-Dur 20. CPF 1043-1069. K-Dur 20, as the only 20 mEq solid dosage potassium chloride product on the market prior to September 2001, enhanced patient convenience by allowing patients to reduce the number of pills they took, and by allowing many patients to reduce their number of daily dosages (in many cases, to a single daily dose). CPF 1057-1061. K-Dur 20 offers a wider and more flexible range of dosing options for patients than do other potassium chloride products. CPF 1062-1064.

Until Schering brought out the K-Dur microencapsulation products, the largest dose that could be safely given was 10 milliequivalents in any solid dosage form. For an 80 milliequivalent dose, one would need to take eight tablets a day, spread over eight

different times. Tr. at 13:2951-52 (Banker); *see also* CX 2 at SP 003043 (K-Dur 20 mEq Review). The significance of K-Dur 20's single 20 mEq dosage form is that patients taking that dosage of K-Dur 20 require fewer dosages per day than would be required for patients taking different dosages (*e.g.*, 10 mEq or 8 mEq) of alternative potassium chloride tablets or capsules. CX 19 at USL 15235 (Klor-Con Tablets 1997 Marketing Plan); Tr. at 1:128 (Goldberg).

Schering marketed this combination of dosing options under the slogan: "the 4-Way K." CX 2 at SP 003043 (K-Dur 20 mEq Review); CX 20 at SP 004044 (1998 K-Dur Marketing Plan); CX 22 at SP 23 00080 (1999 K-Dur 20 mEq Marketing Plan). Schering considered that this variety of dosing options were advantages that K-Dur 20 had over, and made it more convenient than, other potassium chloride products, and marketed it that way. CX 1549 at 24:9-25, 30:10-21, 90:9-16 (DiLascia dep).

3.145. Professor Bresnahan is not aware of any studies comparing the therapeutic effects of taking two 10 mEq Klor Con 10 tablets with taking one 20 mEq K-Dur 20 tablet. (*Id.* at 693; 34 Tr. 8142-8143 (Bresnahan)). Indeed, Professor Bresnahan conducted no econometric analysis comparing the sale of a 10mEq tablet with the 20mEq tablet. (4 Tr. 685-86, 689-690 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.145:

The finding is incomplete, misleading, and contradicted by other evidence to the extent that it implies that an econometric analysis is a more rigorous approach in analyzing the relevant market. Professor Bresnahan is a fellow of the Econometric

Society. Tr. at 3:394 (Bresnahan); CX 804 (curriculum vitae of Professor Bresnahan). Econometric analysis was used in his book, The Economics of New Goods. Tr. at 3:398 (Bresnahan).

Professor Bresnahan recognizes that econometric studies are used "to measure by statistical means which products are particularly close substitutes for which other products. That's a good input into learning where there's market power and where there's not." Tr. at 6:1224 (Bresnahan). In this case, Professor Bresnahan was able to utilize a more direct and reliable method for determining market power. Professor Bresnahan relied on the general economic literature on the effect of A-B rated generic entry, the direct evidence of what occurred when an A-B rated generic for K-Dur 20 entered the market, the assessments of market participants about the effect of entry by an A-B rated generic for K-Dur 20, and the market participant's explanations of the reason for this effect. Tr. at 6:1223-25 (Bresnahan).

Professor Bresnahan rejected the use of econometric analysis because a stronger method of analysis was available.

> Some of the other methods are -- would be hard to use in this matter. Econometric methods that try to say what was particularly effective about competition from the generics have to deal with the problem that there hasn't -- you don't have much in the way of sample size, that's a statistical term, that the -- that the number of months at which -- in which there's been competition whose particular force you might want to try to measure econometrically is limited. So, I chose these because they went with the issue at hand and because I thought the others would be weaker.

Tr. at 6:1224-25 (Bresnahan).

Professor Bresnahan is a distinguished industrial economist possessing all of the

qualifications necessary to determine the amount and reliability of the information required to accurately assess the economic issues in this case. CPRF 3.141.

3.146. Nor did Professor Bresnahan reference or perform any formal surveys of doctors, hospitals, physicians, insurance companies, drug wholesalers, pharmacists, state or federal agencies, prescription benefit managers, or patients to determine their substitution rates of 10mEq tablets for 20 mEq tablets or their usage patterns for various forms of potassium chloride. (*Id.* at 642, 690-92).

Complaint Counsel's Response to Finding No. 3.146:

The finding is incomplete, misleading, and contradicted by other evidence to the extent that it indicates Professor Bresnahan did not study the behavior of potassium supplement consumers. The finding is contrary to more reliable evidence to the extent that it asserts the use of surveys as necessary to examining the economic issues relevant to this case.

Professor Bresnahan reviewed documents containing information on substitution and patterns of usage. These documents are internal documents relied on by the Schering and Upsher to make business decisions.

For example, Professor Bresnahan reviewed and testified about the 1997 K-Dur Marketing Plan, a document produced by Schering, which contains information on substitution and patterns of usage. CX 18; Tr. at 3:455-56 (Bresnahan). Professor Bresnahan reviewed the information in this document regarding possible substitution by physician, pharmacists, and patients of K-Dur 20 with two 10 mEq tablets. CX 18 at SP

23 00049, 58, 63 ("1997 K-Dur Marketing Plan"). He also reviewed information in this document concerning managed care providers patterns of usage. CX 18 at SP 23 00042-44, 48-49. He reviewed the information in this document concerning patterns of usage by physicians, pharmacists, and hypokalemic patients. CX 18 at SP 23 00039, 43-47. He reviewed the information in this document concerning patterns of usage by pharmacy benefit managers, hospitals, federal agencies and state Medicaid plans. CX 18 at SP 23 00039, 42-44. He reviewed the information in this document concerning patterns and practices of drug wholesalers. CX 18 at SP 23 00039, 45.

Professor Bresnahan is a distinguished industrial economist possessing all of the qualifications necessary to determine the amount and reliability of the information required to accurately assess the economic issues in this case. CPRF 288.

Surveys are not the best evidence for examining the economic issues relevant to this case. Professor Bresnahan is aware of the use of surveys in connection with defining the relevant market. Professor Bresnahan considered the reliance on surveys to be a weaker methodology than the general economic literature on the effect of A-B rated generic entry, the direct evidence of what occurred when an A-B rated generic for K-Dur 20 entered the market, the assessments of market participants about the effect of entry by an A-B rated generic for K-Dur 20, and the market participant's explanations of the reason for this effect. Tr. at 6:1223-25 (Bresnahan).

3.147. Professor Bresnahan has no reason to believe that there is any subclass of patients for whom K-Dur 20 was the only appropriate potassium treatment. (6 Tr. 1271 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.147:

The finding is contradicted by the evidence. The fact of Schering's monopoly power demonstrates that many patients are unable to switch to other potassium treatments. Tr. at 34:8057-58 (Bresnahan). Generic substitution for K-Dur 20 was minimal prior to September 2001. CPF 996-1036. Empirical data show that there was no significant substitution of generic drugs for K-Dur 20 prior to September 2001. CPF 1000-1003. There is no evidence of substantial "preemptive" substitution of non-AB-rated generics for K-Dur 20 at the physician level. CPF 1024-1028. Very little generic substitution for K-Dur 20 occurred prior to September 2001, despite payer pressure to cut costs. *See* CPF 932-1128 (complaint counsel's findings that the relevant product market is 20 mEq potassium chloride supplement tablets and capsules, which includes only K-Dur 20 and its AB-rated generic equivalents); Tr. at 34:8057-58 (Bresnahan); CPF 933-936, 938-1076, 1081-1128.

3.148. Professor Bresnahan considers the textbook by Dennis Carlton and Jeffrey Perloff "authoritative on the basic principles of industrial organization." (34 Tr. 8012, 8126 (Bresnahan)). Professor Bresnahan has used this textbook to teach courses in Industrial Organization. (*Id.* at 8012). This text sets forth standard approaches that economists use to define markets. According to Carlton and Perloff, "Numerous methods are used to identify the good substitutes for a particular product. One is to interview producers in the industry who presumably know both their customers and their potential competitors from other industries." (*Id.* at 8129). Professor Bresnahan did not interview any competitors in reaching his conclusions.

(*Id.*). Professor Bresnahan acknowledged, however, that Upsher-Smith executives were capable of determining who their major competitors were in 1997. (*Id.* at 81-8182).

Complaint Counsel's Response to Finding No. 3.148:

The finding is incomplete and misleading. Professor Bresnahan reviewed and addressed market share breakdown from the files of firms engaged in selling potassium supplements. As a distinguished economist, Professor Bresnahan understands that in assessing the relevant market it is a mistake to rely on the word "market" as used by marketeers. Tr. at 34:8010 (Bresnshan) (pointing to the mistaken reliance of Addanki on these kind of documents). *See* CPRF 3.149.

3.149. Further, Professor Bresnahan did not consider Schering's or Upsher-Smith's advertising documents in forming his opinion. (6 Tr. 1225-1226 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.149:

The finding is incomplete. Professor Bresnahan rejected advertising documents as irrelevant to his analysis and explained the reason for his rejection of these documents in the cited testimony. He did not see them as relevant to the "core question" of whether or not Schering had market power. Tr. at 6:1225-1226 (Bresnahan).

Professor Bresnahan rejected the advertising materials because the information continued in the advertisements do not alter the facts that 1) Schering was able to raise the price of K-Dur 20 without losing sales (CPF 972-987); 2) generic K-Dur 20 was forecasted, and did take, substantial sales from K-Dur 20 at a substantial discount (CPF 952-971, 988-992); 3) only generic K-Dur 20 was forecasted, and did, force Schering to lower the price of its 20 mEq

potassium supplement by launching its own generic K-Dur 20 (CPF 993-1036).

3.150. According to Carlton and Perloff, "If products A and B are in the same economic market, then their prices should tend to move closely together. Therefore, a reasonable first step in defining economic markets is to examine the price correlations (a statistical measure of how closely prices move together) among different products." (34 Tr. 8130 (Bresnahan)). Professor Bresnahan agrees that this may be reasonable first step to defining a product market. (*Id.*). However, Professor Bresnahan did not undertake such a statistical analysis. (*Id.* at 8131).

Complaint Counsel's Response to Finding No. 3.150:

The finding is contradicted by other evidence. Professor Bresnahan systematically studied the price information of other potassium manufacturers' potassium products to the extent necessary for a determination as to whether Schering had monopoly power. Specifically, Professor Bresnahan reviewed price information in conjunction with his finding that other potassium chloride supplements did not constrain Schering's pricing of K-Dur 20. Tr. at 3:431-32, 3:475-76, 3:479-481, 3:483, 6:1227-29 (Bresnahan). Professor Bresnahan's finding that other potassium chloride products had little effect on the price of K-Dur 20 explicitly and implicitly includes a systematic consideration of the price of other potassium manufacturers' potassium products. Tr. at 3:475-477 (Bresnahan).

The finding is incomplete and misleading to the extent that it implies any useful information exists in the knowledge of price alone.

Professor Bresnahan systematically studied the price of K-Dur 10, K-Tab 10,

Micro-K 8 and Micro-K 10 for the years 1997 to 2000. Tr. at 34:8033-35 (Bresnahan). Specifically, Professor Bresnahan used the price of K-Dur 20 and the prices of Micro-K 10, Slow-K and K-Tab to calculate the relative prices of these products to K-Dur 20. In conjunction with these calculations, Professor Bresnahan displayed the sales volume of K-Dur 20. CX 1765 (demonstrative); Tr. at 34:8033-34 (Bresnahan). Professor Bresnahan then used the price differential calculations to demonstrate that despite the increasing price differential between K-Dur 20 and these other products, sales of K-Dur 20 continued to increase over this same period while the sales of similarly priced brand name products K-Dur 10, K-Tab 10, Micro-K 8 and Micro-K 10 were flat or decreasing. Professor Bresnahan also showed that Addanki's use of price comparisons is meaningless without showing the relative sales of the products over the same period. Tr. at 34:8033-35 (Bresnahan). This evidence contradicts the finding that Professor Bresnahan did not systematically study the prices of other potassium manufacturers' potassium products. Moreover, he used these prices to determine that the products were not a meaningful constraint on the price of K-Dur 20, an important economic issue relevant to this case.

Professor Bresnahan also testified that from at least 1995 through 2000, branded K-Dur 20 "commanded a substantial price premium over . . . the then existing generics." Tr. at 3:475 (Bresnahan) (discussing historical sales and pricing of K-Dur 20). According to a Schering K-Dur planning document from 1995, "K-DUR is priced 40-50% higher than a comparable generic dose. However, K-DUR's growth has not been significantly impacted by the prevalence of generics in the Therapeutic Class . . .." CX 13 at SP 23 003045 ("K-Dur Long Term Strategy," Mar. 8, 1995 (Andrea J. Pickett, Schering Product

Manager for K-Dur 20); *see also* Tr. at 3:481, 34:8038-8039 (Bresnahan).

3.151. According to Carlton and Perloff, "The direct price elasticity [of demand]. . ., determines market power." (*Id.*). Professor Bresnahan has not calculated the direct price elasticity for any potassium chloride product. (34 Tr. 8131-32 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.151:

The finding is misleading and contradictory to basic economic principles to the extent that it states the Professor Bresnahan "did not study the direct price elasticity between K-Dur 20 and other potassium products." The direct price elasticity of a product is the impact of a percentage change in the price of one product on the percentage change in the quantity demanded of *that same product*. Therefore, a measurement of the elasticity between K-Dur 20 and other potassium products is not a direct price elasticity.

The finding is incomplete and misleading and contradicted by other evidence to the extent that it implies that Professor Bresnahan did not study information relevant to a determination of the direct price elasticity of K-Dur 20 is a more rigorous approach in analyzing the economic issues in this case. *See* CPRF 299.

The finding is contradicted by other evidence to the extent that it implies that Professor Bresnahan did not study the response of the sales of K-Dur 20 to changes in the price of K-Dur 20.

Professor Bresnahan analyzed the change in demand for K-Dur 20 in response to a change in the price of K-Dur 20. Any analysis which "bears on what the products were, what the buyers were doing, what the sellers were doing, what the documents say and so

on, is what it's basically doing *is informing us about elasticity of demand* and cross-elasticity of demand." Tr. at 24:5716 (Addanki) (explaining that he examined the cross-elasticity of demand without performing a *quantitative* or *econometric* analysis (*emphasis added*)).

Professor Bresnahan Professor Bresnahan analyzed the change in demand for K-Dur 20 in response to a change in the price of K-Dur 20 in his finding that K-Dur 20's sales increased even though the price of K-Dur 20 kept rising over this period relative to the prices of most other products. Tr. at 34:8035-37 (Bresnahan) (discussing CX 1765). Professor Bresnahan's finding that K-Dur 20's sales increased even though the price of K-Dur 20 kept rising explicitly includes a systematic consideration of the effect of the increasing price K-Dur 20 on the quantity of sales of other potassium products.

3.152. Professor Bresnahan performed no econometric analysis of cross-elasticity of demand in this case. Indeed, Professor Bresnahan performed no econometric analysis at all in this case. (4 Tr. 685-686, 689-90 (Bresnahan)). Professor Bresnahan did not even perform a quantitative study of the cross-elasticity between K-Dur 10 and K-Dur 20 to determine what effect, if any, the price of one product has on the price of the other. (5 Tr. 810-11 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.152:

The finding is incomplete and misleading and contradicted by other evidence to the extent that it implies that Professor Bresnahan did not study information relevant to a determination of the cross-elasticity of demand between K-Dur 20 and other products. *See* CPRF 299. Professor Bresnahan studied the response of other products sales to increases in the price of K-Dur 20.

The cross-elasticity of demand is the "impact of a percentage change in the price of one product on the percentage change in the quantity demanded of another product." Tr. at 4:687 (Bresnahan). Professor Bresnahan made no quantitative "econometric analysis". Tr. at 4:689-90 (Bresnahan).

Professor Bresnahan analyzed the change in demand between K-Dur 20 and other products in response to a change in the price of K-Dur 20. Any analysis which "bears on what the products were, what the buyers were doing, what the sellers were doing, what the documents say and so on, is what it's basically doing is informing us about elasticity of demand and cross-elasticity of demand." Tr. at 24:5716 (Addanki) (explaining that he examined the cross-elasticity of demand without performing a *quantitative* or *econometric* analysis).

Professor Bresnahan analyzed the demand between K-Dur 20 and other products in finding that other potassium chloride supplements did not constrain Schering's pricing of K-Dur 20. Tr. at 3:431-32, 3:475-76, 3:479-481, 3:483, 6:1227-29 (Bresnahan). Professor Bresnahan's finding that other potassium chloride products had little effect on the price of K-Dur 20 explicitly includes a systematic consideration of the effect of the increasing price K-Dur 20 on the quantity of sales of other potassium products. Tr. at 3:475-477 (Bresnahan). For example, the price of K-Tab 10 and the Micro K products falls relative to K-Dur 20 but the sales from K-Dur 20 continue to rise over the same period. Tr. at 34:8032 (Bresnahan).

Professor Bresnahan also performed an analysis of the demand between K-Dur 20

and other products in finding a substantial "price effect" upon the entry of a 20 mEq generic product for K-Dur 20. Professor Bresnahan's finding of a substantial price effect only after the entry of a 20 mEq generic product for K-Dur 20 implicitly includes a conclusion that the cross-elasticity between the higher priced K-Dur 20 and the lower priced generic 10 and 8 mEq products was extremely low. Tr. at 3:434-436 (Bresnahan).

3.153. Professor Bresnahan is aware of no pharmaceutical trade periodicals that treat K-Dur 20 as a separate product market. (7 Tr. 1271-72 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.153:

The proposed finding is irrelevant. Professor Bresnahan is an industrial organization economist. Tr. at 3:381; 3:407 (Schering counsel John Nields stating, "Dr. Bresnahan is clearly an expert in industrial organization economics."). Professor Bresnahan was hired to assess whether the settlement agreement between Upsher-Smith and Schering-Plough delayed generic entry and harmed competition. Tr. at 3:408 (Bresnahan).

Professor Bresnahan possesses all of the qualifications necessary to determine the amount and quality of information required in assessing the market definition. CPRF 3.141 No evidence has been presented to show that the authors of any pharmaceutical trade periodicals performed any economic analysis in order to define whether K-Dur 20 is not in a separate product market, or that this was the intent of these texts.

b. Substitution costs are low

3.154. Substitution, or "switching," costs are not a material impediment to the substitutability of one potassium chloride product for another, because there is competition at levels other than the pharmacy. (25 Tr. 6162 (Addanki)). The demand for potassium products begins at the point before any switching costs, where a patient seeks treatment for hypokalemia. (20 Tr. 4644 (Dritsas)). The physician writes a prescription for a potassium chloride product, typically in a dose ranging from 15 to 80 milliequivalents per day. (20 Tr. 4644 (Dritsas)). The most common prescribed dosage is 40 mEq. (20 Tr. 4644-45 (Dritsas)). The physician can write the prescription for a brand, or the physician can write an open prescription for a dosage of KCl. (Dritsas 4644). For example, a physician in 1997 may have written "KCl 20 milliequivalents, 40 milliequivalents Q daily." (20 Tr. 4645 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.154:

The finding is contradicted by the evidence. The rate of therapeutic substitution of non-AB-rated generic drugs for K-Dur 20 is very low, because of the effects of state generic drug substitution laws and the higher switching costs attendant to substitution of non-AB-rated drugs, as opposed to AB-rated generic drugs, for a prescribed branded drug. CPF 1004-1005, 1010-1013.

State generic drug substitution laws do not allow the automatic substitution of generic potassium chloride products not AB-rated to K-Dur 20 – *i.e.*, all other potassium chloride products prior to the entry of Upsher in September 2001. Most states have laws that permit a pharmacist to automatically substitute an AB-rated generic drug for its bioequivalent branded drug, unless the prescribing physician indicates "dispense as written" or "DAW." However, those laws do not permit automatic substitution of a non-

AB-rated drug for another drug – to do this, a pharmacist must contact the physician for permission. CPF 34-36. Other forms of potassium chloride (liquids, powders, and effervescent tablets) cannot be substituted automatically for a K-Dur 20 tablet (Tr. at 20:4846-47 (Dritsas); CX 1496 at 55:16-18, 21-24 (Dritsas dep.)). Equivalent dosages of products of other strengths (*e.g.*, two 10 mEq tablets) cannot be substituted automatically for a 20 mEq dosage of K-Dur 20. Tr. at 20:4846 (Dritsas); Tr. at 1:174 (Goldberg); Tr. at 21:5001 (Freese); Tr. at 15:3468 (Ray Russo). A pharmacist cannot substitute these different forms or dosage strengths of potassium chloride for K-Dur 20 without physician permission. Tr. at 1:174 (Goldberg); Tr. at 15:3468 (Russo); Tr. at 20:4846 (Dritsas); Tr. at 21:5001 (Freese).

The inability of pharmacists to automatically substitute non-AB-rated generic potassium chloride products for K-Dur 20, and the "switching costs" this creates, result in the extremely low substitution rate of non-AB-rated generics for K-Dur 20 (*i.e.*, "therapeutic substitution"). CPF 1011-1013, 1016-1023; *see generally* Tr. at 20:4634-35 (Dritsas) ("therapeutic substitution"). The "switching cost" – a cost of switching from one product to another – is lower for dispensing an AB rated generic for K-Dur 20 than for dispensing another potassium chloride for K-Dur 20. The inability of pharmacies to substitute non-20 mEq potassium chloride products for K-Dur 20 without the physician's authorization imposes a switching cost on those who seek to use a non-bioequivalent generic or other potassium chloride product in lieu of K-Dur 20. This cost arises from the need for the patient or pharmacist to consult with, and get the approval of, the physician before substituting a non-AB-rated product. Tr. at 3:490-91 (Bresnahan). Each call a

pharmacist makes costs a certain amount of pharmacist time, resulting in a cost to the pharmacy. Tr. at 21:5001-03 (Freese); Tr. at 20:4847 (Dritsas). Even after the pharmacist has expended the time and the effort contacting physicians for permission to switch from the prescribed drug to a non-AB-rated product, the physician may not agree all of the time. Tr. at 4:698 (Bresnahan).

Schering and Upsher both recognized that an AB-rated generic K-Dur 20 would be a closer competitor to branded K-Dur 20 than other potassium chloride products, because of the lower switching costs. *See, e.g.*, CX 18 at SP 23 00044 (1997 K-Dur Marketing Plan, Sep. 10, 1996) ("the impact of a generic 20 mEq product would be significant, especially for sales subject to mandatory generic substitution laws, Medicaid, and managed care"); CX 21 at USL 12832 (Klor-Con M20 plan, July 1997) ("Klor-Con M20 Tablets are . . . therapeutically and fully substitutable for K-Dur 20. Klor-Con M20 is positioned to be the first quality, low cost alternative to K-Dur 20 representing a better value to the pharmacist"); Tr. at 3:491-93 (Bresnahan) (discussing CX 18).

The proposed finding also is incomplete and misleading. In late 1996 and early 1997, the typical daily dosage of potassium chloride was 20 mEq. With a single extended release K-Dur 20 tablet, a patient could obtain a full day's requirement of potassium. More recently, the optimal dose for the prevention of hypokalemia is considered to be 20 mEq per day, while the optimal dose for the treatment of hypokalemia is 40 to100 mEq. Thus, for patients requiring potassium chloride for prophylaxis against hypokalemia, a single K-Dur 20 tablet per day will suffice. The ability of a patient to take a single daily K-Dur 20 tablet for prevention of hypokalemia has been one of Schering's major selling

points for K-Dur 20. CPF 1058-1059.

3.155. In 1996, over 60 percent of potassium prescriptions were written as "substitution OK." (20 Tr. 4750 (Dritsas); USX 498). This means that prescriptions were either written as generic and without a need for an A-B rated product for substitution, such as "KCl 8 mEqs, three times a day," or written for a brand, such K-Dur, without an indication to "dispense as written." (20 Tr. 4750-51 (Dritsas)). In such cases, the pharmacist was free to fill it with any branded or generic product of her choosing, and there is no switching cost in these prescriptions (20 Tr. 4652 (Dritsas); 24 Tr. 5703 (Addanki); 4 Tr. 698 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.155:

The proposed finding is incorrect. Pharmacists cannot substitute non-AB rated generics for branded drugs, unless they receive specific approval from the physician. The physician does not have to write "dispense as written" ("DAW") to prevent non-AB rated products from being substituted. CPF 34-36; 1017-1018 (excluded evidence). By writing DAW, the physician prevents the pharmacists from substituting AB-rated products for prescribed brands, which would often otherwise be automatic under state law. CPF 1004-1005.

The finding is contradicted by other evidence to the extent that it asserts switching costs are not an impediment to switching. CPRF 3.154.

3.156. At the time a physician writes a prescription, there is no switching cost for the physician to write that prescription. (4 Tr. 697 (Bresnahan)). For example, there are no switching

costs when a physician writes a prescription for two Klor Con 10s rather than one K-Dur 20. (20 Tr. 4652 (Dritsas); (24 Tr. 5703 (Addanki)).

Complaint Counsel's Response to Finding No. 3.156:

The finding is contradicted by other evidence to the extent that it asserts switching costs are not an impediment to switching. CPRF 3.154.

3.157. Currently, doctors and patients may choose among the various forms of potassium chloride according to the patient's needs and preferences. (1 Tr. 127 (Goldberg); 2 Tr. 259 (Teagarden)). A doctor can decide to prescribe a branded potassium supplement rather than a generic. (2 Tr. 261 (Teagarden)). A doctor may choose to prescribe a liquid, powder, tablet, capsule form of potassium chloride depending on a patient's needs and preferences. (2 Tr. 259-60 (Teagarden)). For example, a liquid or effervescent tablet may be appropriate for an elderly person who cannot swallow a tablet easily. (1 Tr. 127 (Goldberg)). Several companies now offer better-tasting fruit-flavored liquid products. (2 Tr. 258 (Teagarden)). Some people simply prefer capsules to tablets. (1 Tr. 127 (Goldberg)).

Complaint Counsel's Response to Finding No. 3.157:

The proposed finding is incomplete and misleading. First, liquid, powder, and effervescent tablet forms make up less than five percent of potassium chloride supplement sales, and do not compete with K-Dur 20. CPF 1043-1048. Second, until September 2001, K-Dur 20 was unique among potassium chloride products in that it had multiple dosing options. It could be taken whole, split in half, dissolved in water, and even sipped through a straw. The "4-Way K" range of dosing options has been one of

Schering's major selling points for K-Dur 20. CPF 1062-1064. Third, K-Dur 20's unique combination of physical characteristics enhanced patient safety, convenience, and compliance as compared with earlier potassium chloride supplements. This led to it being perceived by physicians and patients as differentiated from other potassium chloride supplements. CPF 1037-1070.

3.158. To encourage patient compliance, various forms and dosages of potassium chloride have been engineered. (2 Tr. 208 (Teagarden)). Potassium chloride is typically not well tolerated by patients. (2 Tr. 207 (Teagarden)). The variations between these available potassium chloride products enhance patient acceptance and willingness to take their medication. (1 Tr. 127 (Goldberg)). Merck-Medco's 2001 formulary thus included a range of these potassium chloride products to ensure that a potassium chloride product that is palatable and acceptable to an individual patient is available. (2 Tr. 208 (Teagarden)).

Complaint Counsel's Response to Finding No. 3.158:

The proposed finding is incomplete and misleading. CPRF 3.157.

3.159. There are no switching costs to the pharmacist either to switch between two different brands of potassium. (20 Tr. 4653 (Dritsas)). As a practicing pharmacist, Ms. Freese filled prescriptions with the dosage of whatever product was appropriate or whatever product was in stock. (21 Tr. 4956-57 (Freese)). A pharmacist can still make a therapeutic interchange even if the two products are not A-B rated. (20 Tr. 4694-95 (Dritsas)). In 1997, even if the physician wrote the prescription for K-Dur 20, the pharmacist could still make a therapeutic substitution.

(20 Tr. 4646-47 (Dritsas)). Where substitution is prohibited, a pharmacist can overcome the prohibition simply by making a telephone call to the physician. (20 Tr. 4652, 4695 (Dritsas)). There is no cost to the patient. (24 Tr. 5703 (Addanki)).

Complaint Counsel's Response to Finding No. 3.159:

The proposed finding is contradicted by the evidence. CPRF 3.154.

3.160. Thus, Upsher provides pharmacists with information on therapeutic substitution. (20 Tr. 4647 (Dritsas)). Moreover, some states mandate a therapeutic substitution if there is a lower-cost alternative that is therapeutically equivalent. (20 Tr. 4647 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.160:

The proposed finding is wrong, incomplete, and misleading. State generic drug substitution laws do not allow the automatic substitution of generic potassium chloride products that are therapeutically equivalent but not AB-rated to K-Dur 20 – *i.e.*, all other potassium chloride products prior to the entry of Upsher in September 2001. CPF 34-36. Other forms of potassium chloride (liquids, powders, and effervescent tablets) cannot be substituted automatically for a K-Dur 20 tablet (Tr. at 20:4846-47 (Dritsas); CX 1496 at 55:16-18, 21-24 (Dritsas dep.)). Equivalent dosages of products of other strengths (*e.g.*, two 10 mEq tablets) cannot be substituted automatically for a 20 mEq dosage of K-Dur 20. Tr. at 20:4846 (Dritsas); Tr. at 1:174 (Goldberg); Tr. at 21:5001 (Freese); Tr. at 15:3468 (Ray Russo). A pharmacist cannot substitute these different forms or dosage strengths of potassium chloride for K-Dur 20 without physician permission. Tr. at 1:174 (Goldberg); Tr. at 15:3468 (Russo); Tr. at 20:4846 (Dritsas); Tr. at 21:5001 (Freese). The

inability of pharmacists to automatically substitute non-AB-rated generic potassium chloride products for K-Dur 20, and the "switching costs" this creates, result in the extremely low substitution rate of non-AB-rated generics for K-Dur 20 (*i.e.*, "therapeutic substitution"). CPRF 3.154.

3.161. Pharmacists continuously call doctors' offices to such therapeutic substitutions or change prescriptions. (21 Tr. 4957 (Freese)). Pharmacies compete against one another, and therefore try to provide the best service by responding to patients' concerns regarding medication combinations and cost issues. (21 Tr. 4958 (Freese); (24 Tr. 5703 (Addanki)). Cost is particularly an issue for patients taking potassium, which is typically a long-term prescription and an ongoing cost for the patient. (21 Tr. 4958 (Freese)). Phone calls to doctors' offices for purposes of therapeutic substitution are a service provided by pharmacists, and customers do not pay any "switching costs" for these calls. (21 Tr. 4959 (Freese); 24 Tr. 5703 (Addanki)).

Complaint Counsel's Response to Finding No. 3.161:

The finding is contradicted by other evidence to the extent that it asserts switching costs do not exist, or are not an impediment to switching. CPRF 3.154. Therapeutic substitution of a non-AB-rated generic is less cost-efficient than automatic substitution of an AB-rated generic because of the attendant "switching costs." Tr. at 3:490-93 (Bresnahan). The "switching cost" of switching from one product to another is lower for dispensing an AB rated generic for K-Dur 20 than for dispensing another potassium chloride for K-Dur 20. The inability of pharmacies to substitute non-20 mEq potassium chloride products for K-Dur 20 without the physician's authorization imposes a switching

cost on those who seek to use a non-bioequivalent generic or other potassium chloride product in lieu of K-Dur 20. This cost arises from the need for the patient or pharmacist to consult with, and get the approval of, the physician before substituting a non-AB-rated product. Tr. at 3:490-91 (Bresnahan). Each call a pharmacist makes costs a certain amount of pharmacist time, resulting in a cost to the pharmacy. Tr. at 21:5001-03 (Freese); Tr. at 20:4847 (Dritsas). Moreover, even after the pharmacist has expended the time and the effort contacting physicians for permission to switch from the prescribed drug to a non-AB-rated product, the physician may not agree all of the time. Tr. at 4:698 (Bresnahan). Respondents' documents show that Schering and Upsher both recognized that an AB-rated generic K-Dur 20 would be a closer competitor to branded K-Dur 20 than other potassium chloride products, because of the lower switching costs. *See, e.g.*, CX 18 at SP 23 00044 (1997 K-Dur Marketing Plan, Sep. 10, 1996); CX 21 at USL 12832 (Klor-Con M20 plan, July 1997); Tr. at 3:491-93 (Bresnahan) (discussing CX 18). *See* CPF 1010-1015.

3.162. For many years, Upsher has depended upon this service to sell Klor Con. (21 Tr. 4959, 5005 (Freese)). Because Klor Con 8 and 10 are B-C rated, Upsher talked to pharmacists, managed care organizations and physicians about therapeutic substitution and the economics of using Upsher's products. (20 Tr. 4635 (Dritsas)). The growth of Klor Con has been achieved largely by therapeutic substitution either at the prescribing level or at the pharmacy level. (25 Tr. 6009-10 (Addanki)).

Complaint Counsel's Response to Finding No. 3.162:

The proposed finding's assertion that Klor Con's growth has been achieved largely by therapeutic substitution at the prescribing or pharmacy level is incomplete and misleading. The rate of substitution at the pharmacy level, from prescriptions for K-Dur 20 to generic potassium chloride products, was extremely low as compared with the substitution rates for other potassium chloride brands. CPF 1001.

Moreover, substitution-related data do not bear out respondents' claims that Klor Con or any other generic potassium chloride product took substantial sales away from K-Dur 20 through "preemptive" substitution at the physician level. By its nature, preemptive substitution (*i.e.,* convincing physicians to switch their prescribing patterns from a drug that they currently prescribe to a different drug, with which they may be less familiar (*see* CPF 1024-1028)) is more difficult to measure than therapeutic substitution (*i.e.,* substitution, at the pharmacy level, of a non-AB-rated drug in place of a prescribed drug (*see* Tr. at 20:4634-35 (Dritsas)). Nevertheless, one would expect substantial shifts in prescriptions from K-Dur 20 to Klor Con or other generics to show up in empirical data relating to number and share of prescriptions. However, the data do not show this. First, empirical evidence shows that K-Dur 20's sales and share of potassium chloride sales increased throughout the latter 1990s and 2000. CPF 1076. Second, the empirical data show that the generics that were gaining sales during this period were taking the overwhelming majority of their sales from other branded potassium chloride supplements (all of which had an AB-rated generic competing with them at the time (CX 16 at SP 003543 (K-Dur 20 was the "only branded potassium chloride product with no AB-rated generic")), rather than from K-Dur 20 (to which none of the generics was AB-rated).

CPF 977-983, 1076 (showing that, while sales and shares of sales of K-Dur 20 and the non-AB-rated generics were increasing, sales and shares of sales of other branded potassium chloride supplements were declining).

Regarding Klor Con 10 specifically, its share of total potassium chloride prescriptions ("TRX") declined from 11.5% in 1996 to 10.9% in 2000. CRF 1076; CX 62 at SP 089327. Klor Con 10's share of new prescriptions ("NRX") decreased from 11.1% to 10.7% during the same period. CRF 1076; CX 62 at SP 089325.

Thus, the empirical evidence does not support respondents' claim that Klor Con 10 took substantial sales from K-Dur 20 at either the physician or pharmacy level. CPF 1025-1028 (Upsher's marketing campaign to persuade physicians to prescribe two Klor Con 10's instead of one K-Dur 20 was unsuccessful in switching substantial sales to Klor Con 10).

3.163. Switching was also possible at chains. Pharmacists who work at chain drugstores may also receive incentives, such as discounts or promotions through market share programs, from managed care organizations. (20 Tr.4654 (Dritsas)). A vendor may pay a chain for market share gains. (20 Tr. 4654 (Dritsas)). These programs create incentives to switch prescriptions between two different brands. (20 Tr. 4654 (Dritsas)). Upsher has initiated market share programs, using rebates to increase its market share. (20 Tr. 4654-55 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.163:

The proposed finding is incomplete and misleading. First, not only is the assertion that pharmacists receive incentives for therapeutic substitution unsupported by

the evidence, it is specifically contradicted by the testimony of Mr. Dritsas cited in support of it. Mr. Dritsas was asked: "Is it common or does it happen that sometimes pharmacists get payments or incentives to make substitutions?" He responded: "I don't know of any - I don't know that you would incentivise a pharmacist to make a substitution." Tr. at 20:4654 (Dritsas).

Second, regardless of what incentives may be paid by manufacturers or other vendors, the empirical evidence does not show that they were successful in creating therapeutic substitution of generic potassium chloride products for K-Dur 20 at the pharmacy level. *See* CPF 1001-1002 (one percent or less generic substitution for K-Dur 20, as compared with much higher rates for other branded products). Moreover, the Divisional Manager for Pharmaceutical Purchasing for the Walgreen's pharmacy chain, said under oath that therapeutic substitution at the pharmacy level is much less common than respondents' witnesses have testified, and that it entails substantial switching costs, particularly in time, to the pharmacist. *See* 1019-23 (excluded evidence).

3.164. Managed care is one area where switching was a straightforward and a frequent occurrence. In 1997, some managed care plans did not cover K-Dur. (20 Tr. 4649 (Dritsas)). Upsher was successful in getting Klor Con 8 and 10 listed on some managed care formularies. (20 Tr. 4649 (Dritsas)). Therefore, if a patient received a prescription for K-Dur 20, and his pharmacist discovered that K-Dur 20 was not part of his insurance plan but Klor Con 10 was, the patient could get his prescription filled with Klor Con 10. (20 Tr. 4649-50 (Dritsas)). Indeed, seven out of ten patients at the time were getting prescriptions for something other than K-Dur.

(20 Tr. 4650 (Dritsas)). Either doctors were writing prescriptions for something other than K-Dur, or doctors were writing prescriptions for K-Dur, and patients were having their prescriptions filled with something other than K-Dur. (20 Tr. 4650 (Dritsas)). Upsher considered this result successful. (20 Tr. 4650 (Dritsas)). Indeed, an Upsher document indicates that there has been significant substitution between Klor Con 10 and K-Dur 20 tablets on this basis. (20 Tr. 4752 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.164:

The statement in this proposed finding that most patients were getting prescriptions for something other than K-Dur 20 is irrelevant to the issue of substitution, as well as incomplete and misleading. First, the fact that some doctors "were writing prescriptions for something other than K-Dur" is irrelevant, unless it can be shown that a substantial portion of those prescriptions involved doctors who previously prescribed K-Dur 20 changing their prescribing habits to prescribe Klor Con 10 instead of K-Dur 20. However, as indicated in CPRF 3.162, there is no empirical evidence to support the claim that substantial substitution for K-Dur 20 occurred among physicians. Second, the empirical evidence regarding substitution rates at the pharmacy level flatly contradicts the claim that "patients were having their prescriptions filled with something other than K-Dur." *See* 3.162. In addition, the statement that "there has been significant substitution between Klor Con 10 and K-Dur 20 tablets" also is flatly contradicted by the empirical evidence. *See* 3.162.

The proposed finding is also misleading because non-AB rated generics of branded drugs, which includes other dosage forms or equivalent dosages using other

strengths (*e.g.*, two 10 mEq tablets), cannot be substituted automatically for a branded drug (*e.g.*, 20 mEq dosage of K-Dur 20). CPF 1004-1005, 1007-1009.

3.165. CX 1389 reflects that the total number of prescriptions in 1996 for K-Dur 20 was 8.8 million, and 10.2 million total for all K-Dur products. (CX 1389; 25 Tr. 6208 (Addanki)). Of the 8.8 million, the document indicates that only 2.7 million were prescribed to be dispensed as written. (CX 1389; 25 Tr. 6208-09 (Addanki)).

Complaint Counsel's Response to Finding No. 3.165:

The proposed finding provides evidence in support of, rather than against, a finding of a separate economic market for K-Dur 20. If 2.7 million (about 31%) of 8.8 million prescriptions for K-Dur 20 were prescribed "DAW" by physicians, this means that 6.1 million (69%) prescriptions for K-Dur 20 were free, with physician approval, to have the less expensive, non-AB-rated generics of that time therapeutically substituted for the prescribed K-Dur 20. *See generally* CPF 28-55. However, the empirical data shows that only about one-tenth of one percent of all K-Dur 20 prescriptions were substituted prior to 2001, as compared with much higher substitution rates for other branded products. CPF 1001-1002. All branded potassium chloride supplements other than K-Dur suffered severe declines in prices, unit sales, revenues, and share of sales during the late 1990s. *See* CPRF 3.162; CPF 974-975, 1076. In contrast, during the same period the prices, unit sales, revenues, and share of sales of K-Dur 20 rose annually. *See* CPRF 3.162; CPF 974-975, 1076. The fact that 69% of prescriptions for K-Dur 20 for which lower priced generic products could have been substituted were, nevertheless, filled with branded K-

Dur 20, whereas most other branded products lost most of their sales to generics (*see* CPRF 3.162), is strong evidence that K-Dur 20 was not in the same economic market as the other potassium chloride products.

3.166. Professor Bresnahan's argument that switching costs result in narrow product markets is "just wrong." (24 Tr. 5703 (Addanki); 25 Tr. 6009 (Addanki)). There are many opportunities for switching and the costs of switching are low. Indeed, the term "switching costs" is not even used in the pharmaceutical industry. (20 Tr. 4653 (Dritsas)). Far from switching costs, there can actually be savings to the consumers when substitutions are made at the pharmacy level. (20 Tr. 4653 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.166:

The proposed finding is misleading, and also is contradicted by other evidence. First, it misrepresents Professor Bresnahan's definition of the relevant market as being based solely on the issue of switching costs. In fact, Professor Bresnahan's conclusion that K-Dur 20 had monopoly power is based on a number of considerations, including: (1) the almost insignificant levels of generic substitution for K-Dur 20 prior to September 2001, compared with the extremely large and rapid substitution of the AB-rated generic Klor Con M20 that were predicted by respondents, and actually occurred, after Klor Con M20's entry in September 2001 (*see* Tr. at 3:430, 3:439-40, 3:3:470-473, 3:480, 3:484, 3:490-93, 34:8038-39 (Bresnahan); CPF 988-993, 996-1036); (2) the inability of other potassium chloride products to restrain K-Dur 20 competitively, as demonstrated by its annual price, sales, and profit increases in the face of generics priced at a fraction of K-

Dur 20's price (*see* Tr. at 3:431-32, 3:475-76, 3:479-81, 3:483, 4:729-31, 5:851-52, 6:1227-30 (Bresnahan); CPF 972-983); and (3) the perceptions of payers, physicians, and patients that other potassium chloride supplements were not good substitutes for K-Dur 20. *See* Tr. at 3:478, 3:484, 6:1173 (Bresnahan); CPF 1024-1037,1069-1070, 1119-1123.

Second, the proposed finding is contradicted by other evidence to the extent that it asserts switching costs do not exist and are not an impediment to switching. CPRF 3.154.

Third, while there may be "opportunities for switching" involving branded potassium chloride products other than K-Dur 20, the empirical evidence show that these opportunities did not exist in the 20 mEq potassium chloride tablet and capsule market prior to the entry of an AB-rated generic K-Dur 20 in September 2001. CPRF 3.162-3.165.

c. Professor Bresnahan improperly defines the market based on pricing differentials between brands and generics

3.167. Professor Bresnahan also did not include 10 mEq products in the same market as 20 mEq products because of a perceived price differential between them. (25 Tr. 6187 (Addanki)). Professor Bresnahan referred to a 30 percent price differential between products as enough to put two different products into separate markets. (25 Tr. 6187 (Addanki)). Charging a higher price than other firms in the market it does not mean, however, that the higher-priced product is in a different market the lower-priced products. (24 Tr. 5740 (Addanki).

Complaint Counsel's Response to Proposed Finding 3.167

The proposed finding is misleading in its oversimplification of Professor

Bresnahan's testimony. In fact, Professor Bresnahan's conclusion that K-Dur 20 had monopoly power is based on a number of considerations, including: (1) the almost insignificant levels of generic substitution for K-Dur 20 prior to September 2001, compared with the extremely large and rapid substitution of the AB-rated generic Klor Con M20 that were predicted by respondents, and actually occurred, after Klor Con M20's entry in September 2001 (*see* Tr. at 3:430, 3:439-40, 3:3:470-473, 3:480, 3:484, 3:490-93, 34:8038-39 (Bresnahan); CPF 988-993, 996-1036); (2) the inability of other potassium chloride products to restrain K-Dur 20 competitively, as demonstrated by its annual price, sales, and profit increases in the face of generics priced at a fraction of K-Dur 20's price (*see* Tr. at 3:431-32, 3:475-76, 3:479-81, 3:483, 4:729-31, 5:851-52, 6:1227-30 (Bresnahan); CPF 972-983); and (3) the perceptions of payers, physicians, and patients that other potassium chloride supplements were not good substitutes for K-Dur 20. *See* Tr. at 3:478, 3:484, 6:1173 (Bresnahan); CPF 1024-1037,1069-1070, 1119-1123.

3.168. Professor Bresnahan failed to define the market using his own "30% pricing differential" criterion. In January 2002, Rite Aid in Washington, D.C. sold K-Dur 20 for $60.99 and Klor Con M20 for $40.99, a 33% difference. According to Professor Bresnahan's logic, K-Dur 20 and its AB-rated generic, Klor Con M20, could not be in the same market. (24 Tr. 5741 (Addanki); 25 Tr. 6187-88 (Addanki)). Nonetheless, Professor Bresnahan concludes that K-Dur 20 and Klor Con M20 are in the same product market. (5 Tr. 1005-06 (Bresnahan)).

Complaint Counsel's Response to Proposed Finding 3.168

The proposed complaint is misleading in its oversimplification of Professor

Bresnahan's testimony. *See* CPRF 3.167. Also, K-Dur 20 and Klor Con M20 are proven to be in the same market by the drastic erosion to K-Dur 20's sales upon the entrance of Klor Con M20. CPF 989-992.

Total Prescriptions

20 mEq Tablets and Capsules

Product	July	August	September	October	November
K-Dur 20	1,001,000	936,000	677,000	429,000	337,000
Generic K-Dur 20	0	0	167,000	476,000	524,000
Total	1,001,000	936,000	844,000	915,000	861,000

CPF 989; CX 1480 at SP 089838.

Also, Klor Con M20 forced Schering to effectively reduce the price of K-Dur 20 by offering K-Dur 20 as a generic product through its Warrick subsidiary. *See* Tr. at 3:439-40 (Bresnahan). The generic potassium chloride products that existed prior to Klor Con M20's entry were unable to affect K-Dur's sales or pricing in this way. *See* CPF 972-987.

3.169. Professor Bresnahan also did not include in his defined market other oral potassium chloride supplements that were priced at equivalent or higher levels than K-Dur 20 for an equivalent dosage, such as K-Dur 10 and K-Tab 10. (24 Tr. 5741 (Addanki); SPX 2069) (demonstrative). According to IMS data, the highest priced potassium chloride product in 1997

was K-Tab 10. (SPX 2071 (demonstrative); 24 Tr. (Addanki)).

Complaint Counsel's Response to Proposed Finding 3.169

The proposed finding is misleading. Professor Bresnahan did not include other non AB-rated potassium chloride products in his defined relevant market because they did not compete with K-Dur 20. The fact is despite K-Dur 20's substantial price premium, non AB-related potassium chloride products were not able to erode K-Dur 20 sales, in fact its sales increased before the entry of an AB-rated generic competitor. *See* CPRF 3.37; 3.168. In addition, the proposed finding's assertion that K-Dur 10 and K-Tab 10 were priced higher than K-Dur 20 is contradicted by other, empirical evidence on average selling price, net direct price, and average wholesale price:

Average Selling Price of Potassium Chloride Products in 1996

Brand	ASP in dollars/units
K-Dur 20	.3285
Klor-Con 10	.0657
Ethex	.0545
Apothecon	.0570
Micro K 10	.1165
K-Tab	.2700
Klotrix	.2000

Source: CPF 1075.

Moreover, as Professor Bresnahan testified, it is not enough to look merely at the prices of other products – one must also consider their sales volume in order to determine their competitive significance. Tr. at 34:8031-33 (Bresnahan); CPF 1108. During the

late 1990s, the sales of the other branded potassium chloride products were small relative to K-Dur 20, and those sales were declining. Tr. at 34:8033-35 (Bresnahan); CPF 1108. In addition, at various times during this period, the prices of certain other branded products fell relative to K-Dur 20, effectively creating a price cut relative to K-Dur 20. CPF 1108. Moreover, the price of K-Dur 20 relative to Klor Con 10 and Klor Con 8 rose during this period. Tr. at 34:8035-36. However, instead of either reducing its price to compete with these products or losing sales to them, K-Dur's sales and prices kept rising over this period. Tr. at 34:8035-37 (Bresnahan); CPF 1108. This is strong evidence that these other products were "not putting an important constraint on K-Dur [20]" (Tr. at 34:8034-35 (Bresnahan)), and is evidence for, rather than against, K-Dur 20's market power. Tr. at 34:8037-38 (Bresnahan).

2. K-Dur's Pricing Does Not Reflect Monopoly Power

3.170. Professor Bresnahan's alternative method of determining the existence of monopoly power involves the relationship between pricing and marginal costs. He defines monopoly power as the ability to price profitably above cost without constraints from competition. (6 Tr. 1189 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.170:

Complaint counsel has no specific response.

a. Complaint counsel did not prove that K-Dur 20 is priced above marginal costs

3.171. Professor Bresnahan's measure of marginal cost excludes several important features of the branded company's true cost to make the product. He excludes research and development costs, for example. (6 Tr. 1190 (Bresnahan)). Professors Areeda and Turner, however, explain that when attempting to infer market power from price-cost comparisons, one must compare the price to the cost of production, research and development costs, and promotional expenses. (6 Tr. 1191, 1193 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.171:

The proposed finding is incomplete and misleading. Professor Bresnahan explained that the Areeda and Hovenkamp example differed from his own analysis of market power, in that it is simply a method for inferring market power from cost-price accounting data (which he indicated is generally not a good idea), and not an analysis of the appropriate definition of marginal cost for determining whether market power exists. Tr. at 6:1191-93 (Bresnahan).

3.172. Complaint counsel failed to present any proof regarding Schering's costs. There is no evidence of what it costs to produce K-Dur 20, and it is therefore impossible to determine how the price of K-Dur 20 compares to its costs.

Complaint Counsel's Response to Finding No. 3.172:

The proposed finding is not supported by the evidence. CX 695 (SP 020696-702) provides the following actual cost information for K-Dur for the years, 1995 – 2nd quarter of 2001: standard direct cost, standard fixed cost, royalties, returns, package revisions, journals, direct mail, agency fees, selling aids, educational materials, samples, promotion,

field selling, incentives, market research, research studies, cash discount, and freight. Schering's marketing plans assume that Schering could still sell K-Dur 20 profitably, even after effectively reducing the price by 50 percent (by selling it as a generic product through Schering's generic arm, Warrick). *See, e.g.*, CX 144 at SP 22 00001-05; [redacted]; *see also* Tr. at 25:5965-80 (Addanki) (Schering forecasts assumed that generics of K-Dur 20 would enter the market at about 50% of the price of K-Dur 20 and capture 50% of the market, and that Warrick would win back 50% of the generic sales). The fact that Schering could effectively reduce the price of K-Dur 20 by 50 percent to compete with entry by an AB-rated generic suggests that it could have reduced the price similarly in response to competition from other potassium chloride supplements, if those products had been in the same product market as K-Dur 20. The fact that it did not reduce K-Dur 20's price (and, in fact, consistently raised that price) suggests strongly that K-Dur 20 was priced well above marginal cost, and that it had market power.

b. Generic substitution does not indicate monopoly power

3.173. Having failed to examine evidence of Schering's actual costs, Professor Bresnahan argues that where a low-priced generic enters and takes sales away from the branded product, it indicates that the branded price is supracompetitive. (3 Tr. 473, 458 (Bresnahan)). According to Professor Bresnahan, this shows that the branded product had monopoly power.

Complaint Counsel's Response to Finding No. 3.173:

Proposed findings 3.173 through 3.175 are incomplete and misleading. They misrepresent Professor Bresnahan's opinion that K-Dur 20 had market power as being based solely on whether a generic product entering the market will take sales away from the branded product. In fact, Professor Bresnahan's conclusion that K-Dur 20 had monopoly power is based on a number of considerations, including: (1) the almost insignificant levels of generic substitution for K-Dur 20 prior to September 2001, compared with the extremely large and rapid substitution of the AB-rated generic Klor Con M20 that were predicted by respondents, and actually occurred, after Klor Con M20's entry in September 2001 (*see* Tr. at 3:430, 3:439-40, 3:3:470-473, 3:480, 3:484, 34:8038-39 (Bresnahan); CPF 988-993, 996-1036); (2) the inability of other potassium chloride products to restrain K-Dur 20 competitively, as demonstrated by its annual price, sales, and profit increases in the face of generics priced at a fraction of K-Dur 20's price (*see* Tr. at 3:431-32, 3:475-76, 3:479-81, 3:483, 4:729-31, 5:851-52, 6:1227-30 (Bresnahan); CPF 972-983); and (3) the perceptions of payers, physicians, and patients that other potassium chloride supplements were not good substitutes for K-Dur 20. *See* Tr. at 3:478, 3:484, 6:1173 (Bresnahan); CPF 1024-1037,1069-1070, 1119-1123.

3.174. Professor Bresnahan concluded that Schering's K-Dur 20 had monopoly power because Klor Con M20, the AB rated generic substitute, came in at a lower price than K-Dur 20 and took sales away from K-Dur 20. (24 Tr. 5736 (Addanki); (CX 1586); 6 Tr. 1180-81 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.174:

Proposed findings 3.173 through 3.175 are incomplete and misleading, because they misrepresent Professor Bresnahan's opinion that K-Dur 20 had market power as being based solely on whether a generic product entering the market will take sales away from the branded product. *See* CPRF 3.173.

3.175. But Professor Bresnahan never explained how the loss of sales to a generic establishes that K-Dur 20's price was above the competitive level. It is very common to find generics on store shelves, and they are almost always at lower prices than brand products. (24 Tr. 5751 (Addanki)). These generic products usually take share from branded products that are sold at higher prices; that does not make each of these brands monopolists. (24 Tr. 5751-52 (Addanki)).

Complaint Counsel's Response to Finding No. 3.175:

Proposed findings 3.173 through 3.175 are incomplete and misleading, because they misrepresent Professor Bresnahan's opinion that K-Dur 20 had market power as being based solely on whether a generic product entering the market will take sales away from the branded product. *See* CPRF 3.173.

3.176. There are plenty of examples of brands taking sales from other brands in the oral potassium chloride supplement market. For example, IMS data reported that from December 1994 to December 1995 the share of new prescriptions accounted for by K-Dur 10 and K-Dur 20 increased from 4.1 to 5.1 percent and from 29.7 to 32.3 percent, respectively. Other products with increasing share included Klor Con 10 and the category labelled "Generic KCL." This

increase in share and sales was associated with significant declining share (and absolute sales) for several other products, including Micro K 10, Micro K, Slow K, K-Tab, Klor Con 8, Klotrix, Ten-K, K-Lease, Kaon-CL and potassium chloride liquids and powders. (CX at 81 SP 089318); CX 81 SP 089319: pattern for total prescriptions). A similar pattern of share and sales movements held for December 1995-December 1996. (CX 82 at SP 089321-322)

Complaint Counsel's Response to Finding No. 3.176:

The proposed finding is irrelevant and contradicted by more reliable evidence. First, since the mid-1990s, the trend in sales of branded potassium chloride products has gone toward 20mEq tablets and capsules (i.e., K-Dur 20, until September 2001) (*see, e.g.*, CX 1493 at 28:12-21 (Dolan Dep.)). This shift in demand from various formulations of potassium chloride to K-Dur 20, is a result of K-Dur 20's unique physical characteristics. These attributes are attractive to physicians, patients, and payers. CPF 1037-1070.

Second, the fact that K-Dur 20's sales and share of sales increased over time, despite K-Dur 20's sizeable price premium over the generic 8 and 10 mEq products. At the same time, branded 8 and 10 mEq products lost sales and share to the generics. This is is strong evidence of two things: (1) that K-Dur 20 was in a different product market from these other products; and (2) that K-Dur 20 had market power in its own market – 20 mEq tablets and capsules. *See* CPRF 3.173.

Third, although both K-Dur 20 and generic products were gaining sales and share of sales from at least 1996 through 2000, the great majority of the lost sales experienced by the branded potassium chloride products went to the generics, for which each branded product other than K-Dur had an AB-rated version (*see* CX 16 at SP 003543 (K-Dur 20

was the "only branded potassium chloride product with no AB-rated generic")), rather than to K-Dur 20 (to which none of the generics or other brands was AB-rated). *See* CX 16 at SP 003543; CPF 977-983, 1076 (showing unit sales and shares of sales of K-Dur 20, its non-AB-rated generics, and the other branded potassium chloride supplements). Moreover, the fact that the other branded potassium chloride products reduced their prices substantially to compete with their generic equivalents (*see* CX 19 at USL 15228 ("major brands have started to trade price for volume to compete with strong generic competition")), but that K-Dur 20 did not (*see* Tr. at 3:431-32, 3:475-76, 3:479-81, 3:483, 5:851-52, 6:1227-30 (Bresnahan); CPF 972-983 (K-Dur 20's price increased annually, despite presence of generics priced at a fraction of K-Dur 20's price); *see also* CPRF 3.214 (K-Dur 20 rebates did not substantially reduce its price vis-a-vis other potassium chloride products)), suggests strongly that the generics were competing with the branded products (but not K-Dur 20), and that most of those brands' lost sales went to the generics, rather than to K-Dur 20.

3.177. Professor Bresnahan acknowledged that when K-Dur 20 was introduced it took business from the incumbent potassium chloride supplements. (6 Tr. 1174-75 (Bresnahan)). According to Professor Bresnahan's test for monopoly each of the firms losing significant share had a monopoly; this is incorrect. (24 Tr. 5739, 5901, 5907 (Addanki)).

Complaint Counsel's Response to Finding No. 3.177:

The proposed finding is misleading to the extent it fails to acknowledge that the very loss of sales of incumbent potassium chloride supplements to a higher priced K-Dur

shows K-Dur's market power. Proposed finding 3.177 is misleading and incomplete to the extent that it misrepresents the factors underlying Prof. Bresnahan's analysis of market power. Tr. at 3:429- 83 (Bresnahan) Proposed findings 3.173 through 3.187 are also incomplete and misleading, because they misrepresent Professor Bresnahan's opinion that K-Dur 20 had market power as being based solely on whether a generic product entering the market will take sales away from the branded product. *See* CPRF 3.173.

3.178. In applying his test, Professor Bresnahan only looked at the volume trends of K-Dur 20 and Klor-Con M20. Professor Bresnahan disregarded other volume trends in the oral potassium chloride supplement market in 2001. (24 Tr. 5737 (Addanki)). To be consistent with Professor Bresnahan's theory, one would have to assume that it was the introduction of Klor Con M20 that was causing the drop K-Dur 20's volume and that nothing was happening to 10 mEq potassium chloride supplements. (24 Tr. 5737 (Addanki)). However, while K-Dur 20 sales were dropping after the entry of Klor Con M20, the sales of other potassium products, including Klor Con 10 and Klor Con 8, were growing. (SPX 2282 (demonstrative); 24 Tr. 5738 (Addanki)). Klor Con M20 was also growing. (24 Tr. 5738 (Addanki); SPX 2282) (demonstrative). Many products were taking sales away from K-Dur 20, not just the AB rated generic, indicating that Professor Bresnahan's test for market power and monopoly was incorrect. (24 Tr. 5739, 5901, 5907 (Addanki)).

Complaint Counsel's Response to Finding No. 3.178:

The proposed finding is incomplete and misleading, because it misrepresents Professor Bresnahan's opinion that K-Dur 20 had market power as being based solely on

whether a generic product entering the market will take sales away from the branded product. *See* CPRF 3.173.

The proposed finding is also contradicted by other evidence, to the extent it asserts that Professor Bresnahan disregarded sales volume-related information in forming his opinion that K-Dur 20 had market power. *See, e.g.*, Tr. at 3:475 (Bresnahan) (He considered information on "sales and pricing" for "potassium chloride products generally," not just K-Dur and Klor Con). In fact, Professor Bresnahan criticized Dr. Addanki's analysis for not considering unit sales information. *See* Tr. at 34:8031-37 (Bresnahan) (discussing how it is necessary to consider the unit sales, not just prices, of other branded potassium chloride products to determine their competitive significance vis-a-vis K-Dur 20).

Regarding the assertion that K-Dur 20 lost substantial sales to other potassium chloride products, including Klor Con 8 and Klor Con 10, the proposed finding is not supported by the evidence and is irrelevant. The empirical data show that, during the latter 1990s and 2000, K-Dur 20's sales and share of sales were increasing steadily. *See* CPF 977-983, 1076 (showing increasing sales and shares of sales of K-Dur 20). Empirical evidence also shows that the generics that were gaining sales were taking the overwhelming majority of their sales from branded potassium chloride supplements (all of which had an AB-rated generic competing with them at the time (*see* CX 16 at SP 003543 (K-Dur 20 was the "only branded potassium chloride product with no AB-rated generic")), rather than from K-Dur 20 (to which none of the generics was AB-rated). *See* CPF 977-983, 1076 (showing that, while sales and shares of sales of K-Dur 20 and the

non-AB-rated generics were increasing, sales and shares of sales of other branded potassium chloride supplements were declining). That there are other changes between different groups of potassium chloride is largely irrelevant. In the summer of 2001, as both Schering and Upsher acknowledge in their proposed findings, although the sales of both K-Dur 20 and K-Dur 10 began dropping and sales of Klor Con 10 and Klor Con 8 showed an upturn about the same time, this was due primarily to a shortage of K-Dur products due to FDA compliance issues that arose during the summer of 2001 (*see* Schering's Proposed Finding No. 3.180; Upsher's Proposed Findings No. 179-182), which required therapeutic substitution of other products for the unavailable K-Dur 20. *See* Schering's Proposed Finding No. 3.180; CPF 1023 (excluded evidence). Moreover, the assertion that K-Dur 20 lost share to Klor Con 8 and Klor Con 10 is contradicted by Upsher's Proposed Finding No. 196, which states that Upsher's "8 mEq and 10 mEq wax matrix products" (i.e., Klor Con 8 and Klor Con 10) "lost market share and sales to K-Dur 20."

Moreover, even if it can be shown that Klor Con and other non AB-rated generics took some sales from K-Dur 20, this fact by itself is not meaningful for an analysis of whether those firms and K-Dur 20 competed in the relevant economic market, and whether K-Dur 20 had monopoly power in that market. *See* CPF 1086-1089 (explaining how the conclusion that the mere presence of competing firms in a monopoly market where the dominant firm is pricing at monopoly levels means that the market is competitive commits the basic analytical error known as the "cellophane fallacy"). Also, the mere fact that non-AB-rated generics were K-Dur 20's closest competitors prior to

September 2001 does not imply that they were good substitutes for K-Dur 20, since at monopoly prices, even poor substitutes start looking good to some customers. *See* CPF 1089 (Posner (used as reliable authority)).

3.179. Sales of K-Dur 10 also fell after the introduction of an AB-rated generic, Klor Con M10. (SPX 2284 (demonstrative); 24 Tr. 5739 (Addanki)). But K-Dur 10 did not have monopoly power. (24 Tr. 5740 (Addanki)). The Bresnahan test therefore leads to the wrong conclusions. (24 Tr. 5740 (Addanki)).

Complaint Counsel's Response to Finding No. 3.179:

The proposed finding is incomplete and misleading, because it misrepresents Professor Bresnahan's opinion that K-Dur 20 had market power as being based solely on whether a generic product entering the market will take sales away from the branded product. *See* CPRF 3.173.

The proposed finding is also misleading to the extent that it suggests that only a monopolist will lose sales to a new entrant and it fails to acknowledge that the introduction of new AB rated generic opened up K-Dur 10 to new competition.

K-Dur's sales decline in mid-2001 was the result of FDA regulatory action, not competition from other potassium chloride supplements. *See* Schering's proposed finding 3.180; Upsher's Proposed Findings No. 180-182. This supply shortage forced pharmacists to rely on the therapeutic substitution of other products for the unavailable K-Dur 20. *See* Schering's Proposed Finding No. 3.180; CPF 1023 (excluded evidence).

Nevertheless, when Upsher entered with its lower-priced generic version of K-Dur 20 in September 2001, Schering's sales suffered a rapid and dramatic decline, losing nearly two-thirds of new prescriptions, and over 50% of total prescriptions, for 20 mEq potassium chloride tablets in just over two months. CX 5 at Schering-Plough 089313-13c; CX 6 at SP 089314-17. This result was consistent with how generic entry typically effects the brand's market share. *See* CPF 39-41, 50-55

3.180. In looking at generic substitution for K-Dur 20, Professor Bresnahan ignores the fact that Schering's K-Dur 20 was not as widely available as a result of manufacturing problems, which compromised Schering's ability to supply K-Dur to the marketplace. (23 Tr. 5488-89 (Troup)) (20 Tr. 4682, 4823, 4826-27 (Dritsas)). A sales history shows K-Dur 20's prescriptions dropping since July 2001, before Upsher's entry. (20 Tr. 4823 (Dritsas); CX 1586). During this time, Upsher saw its sales of Klor Con 8 and 10 double. (20 Tr. 4682, 4823-24 (Dritsas)). Upsher's customers were switching K-Dur 20 for two Klor Con 10s, because K-Dur 20 was not available. (20 Tr. 4682-83 (Dritsas)). Indeed, Walgreen's system was set up to instruct the pharmacist to dispense Klor Con 10 when a prescription for K-Dur 20 was received. (20 Tr. 4683 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.180:

The proposed finding is incomplete and misleading, because it misrepresents Professor Bresnahan's opinion that K-Dur 20 had market power as being based solely on whether a generic product entering the market will take sales away from the branded product. *See* CPRF 3.173. The proposed finding is also misleading because it fails to

acknowledge difference in magnitude of the sales changes before September 2001 and after September 2001: small changes before then were due to product availability problems, but the big decline came only after availability of an AB rated generic.

Moreover, K-Dur's sales decline in mid-2001 was the result of FDA regulatory action, not competition from other potassium chloride supplements. *See* CPRF 3.179. Prior to that time, K-Dur 20's share of sales had been increasing, while the shares of Klor Con 8 and 10 had been relatively flat. *See* CPF 977-983, 1076 (showing that sales and shares of sales of K-Dur 20 and the non-AB-rated generics were increasing, and that sales and shares of sales of other branded potassium chloride supplements were declining). The fact that sales of Klor Con 10 and Klor Con 8 increased substantially only after K-Dur 20 was physically unavailable to be dispensed, thereby making therapeutic substitution a necessity rather than a choice, is strong evidence that purchasers and physicians did not regard these products as close substitutes for K-Dur 20.

3.181. Professor Bresnahan also conceded that the competition that exists between a brand name company and its AB rated generic has special features. (6 Tr. 1176 (Bresnahan)). Nonetheless, Professor Bresnahan did not account for mandatory substitution laws. Most states allow pharmacists to make a therapeutic substitution in their professional judgment, and in some states, mandatory substitution laws require pharmacists to dispense the generic product when filling a prescription for the branded product. (17 Tr. 4034-35 (Dritsas); 20 Tr. 4634-35) (Dritsas); 6 Tr. 1178 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.181:

The proposed finding is misleading and contradicted by more reliable evidence to the extent it suggests that state substitution laws are not restricted to AB rated generics. The generic substitution laws only require switching when the AB rated generic is less expensive. The switching comes about because the brand chooses not to compete on price. State generic drug substitution laws do not allow the automatic substitution of generic potassium chloride products not AB-rated to K-Dur 20 – i.e., all other potassium chloride products prior to the entry of Upsher in September 2001. CPF 1005. Most states have laws that permit a pharmacist to automatically substitute an AB-rated generic drug for its bioequivalent branded drug, unless the prescribing physician indicates "dispense as written" or "DAW." However, those laws do not permit automatic substitution of a non-AB-rated drug for another drug – to do this, a pharmacist must contact the physician for permission. CPF 34-37. At the time of the Schering/Upsher agreement, no potassium chloride supplement was AB-rated, and therefore none was automatically substitutable, for K-Dur 20. *See, e.g.*, CX 1493 at 41:12-16 (Dolan dep.) (K-Dur 20 "was the only product that was . . . 20 mEq on the marketplace at the time. . . . [I]t was not AB rated to anything else and not fully substitutable for any other products . . . ."); CX 16 at SP 003543, SP 003545 "(K-Dur Marketing Research Backgrounder," dated July 1, 1996) (K-Dur 20 has "no AB rated generic," and "cannot be legally substituted"); Tr. at 15:3466-68 (Russo). A pharmacist cannot substitute these different forms or dosage strengths of potassium chloride for K-Dur 20 without physician permission. Tr. at 1:174 (Goldberg); Tr. at 15:3468 (Russo); Tr. at 20:4846 (Dritsas); Tr. at 21:5001 (Freese).

Furthermore, the proposed finding is inaccurate and contradicted by more reliable

evidence proving that pharmacists may not make therapeutic substitutions at will. "Therapeutic substitution involves filling a prescription with a drug that differs in chemical composition, dosage strength, and/or dosage form from the drug that the physician [has] prescribed." CX 1778 ¶ 11 (Declaration of William E. Groth, Divisional Manager for Pharmaceutical Purchasing for Walgreen Co. ("Groth Declaration") – excluded evidence). Mr. Groth disagreed with Lori Freese's testimony that potassium chloride products of different strengths and dosage forms are interchangeable in the real world:

Ordinarily, prescriptions include the product or chemical entity, as well as the dosage form (i.e. tablets, capsules, liquid, or powder) and strength (i.e., 20 mEq.). If a pharmacist wants to fill the prescription outside these parameters, then this is a therapeutic substitution and the pharmacist must receive physician approval. CX 1778 ¶ 7 (Groth Declaration – excluded evidence).

Mr. Groth is "not aware of any state that permits a pharmacist to make a therapeutic substitution without physician approval." CX 1778 ¶ 12 (Groth Declaration – excluded evidence). Based on his knowledge of how Walgreens pharmacists operate on a day-to-day basis, through both his current position and 13 years as a pharmacist in Walgreens stores, Mr. Groth stated that Lori Freese's testimony that one of a pharmacist's major responsibilities is to call physicians to seek approval for therapeutic substitutions is not correct with respect to Walgreens pharmacists. CX 1778 ¶ 7 (Groth Declaration – excluded evidence). While it is sometimes necessary for pharmacists to contact physicians for other reasons, therapeutic substitution by pharmacists is unusual. CX 1778

¶7, 11, 14 (Groth Declaration- excluded evidence).

Walgreens does not promote therapeutic substitution, and "such substitution is unusual" for Walgreens pharmacies. CX 1778 ¶ 11 (Groth Declaration- excluded evidence). Mr. Groth stated that "Walgreens believes that its pharmacists should not interfere in the physician-patient relationship. If the physician has determined that a particular product is the most appropriate agent for a patient, the pharmacist should not second guess that decision without a compelling reason, such as product unavailability." CX 1778 ¶ 13 (Groth Declaration- excluded evidence).

Mr. Groth is not aware of any instance in which Walgreens has required its pharmacists to make a therapeutic substitution. CX 1778 ¶ 11 (Groth Declaration - excluded evidence). He stated that during the summer of 2001 there was a shortage of K-Dur 20. During that time, individual Walgreens pharmacists who were unable to obtain K-Dur 20 implemented therapeutic substitution with the physician's approval. If a generic formulation of potassium chloride 20 mEq had been available, the pharmacists would have filled those prescriptions with an AB-rated generic equivalent instead of a therapeutic substitute. CX 1778 ¶ 16. (Groth Declaration - excluded evidence). According to Mr. Groth, Phillip Dritsas' testimony that Walgreens set a message in its system so that when the prescription came up for K-Dur, the pharmacists were instructed to dispense two Klor Con 10 products, is erroneous. CX 1778 ¶ 8 (Groth Declaration- excluded evidence).

3.182. Where pharmacists are required to substitute the generic for the branded product,

a prescription for K-Dur 20 will result in an automatic switch by the pharmacist to the generic product. (6 Tr. 1178 (Bresnahan)). Thus, generics always take sales away from the brand name (6 Tr. 1180 (Bresnahan)), even if the patient preferred the brand. (24 Tr. 5742-49 (Addanki)).

Complaint Counsel's Response to Finding No. 3.182:

The proposed finding is contradicted by other evidence, to the extent it asserts that state generic drug substitution laws force patients to purchase AB-rated equivalents of branded products, even when the patients or their physicians want the branded products to be prescribed. First, even in mandatory substitution states, the AB rated generic substitution is only mandated for prescriptions filled under third-party payor plans. The proposed finding is misleading and contradicted by other evidence, to the extent it asserts that state generic drug substitution laws force patients to purchase AB-rated equivalents of branded products, even when the patients or their physicians want the branded products to be prescribed. First, some state generic substitution laws are not mandatory, but permit the pharmacist discretion in substitution. *See* CPF 37. Second, physicians can require that prescriptions be dispensed with the branded product, rather than a generic, simply by writing "dispense as written" (or "DAW") on the prescription. *See* CPF 37-38. Third, state generic substitution laws do not require a generic product to be dispensed if a patient requests the branded product. *See* CPF 38. State generic drug substitution laws merely implement the basic economic principle that, given a choice between two fundamentally identical products, consumers typically will choose the less expensive one, particularly when it is priced at half the price of the alternative product. *See* CPF 990, 1113 (generic K-Dur 20 is priced at 50% of the branded price).

What these proposed findings ignore is that state generic drug substitution laws merely implement the basic economic principle that, given a choice between two fundamentally identical products, consumers typically will choose the less expensive one, particularly when it is priced at half the price of the alternative product. *See* CPF 990, 1113 (generic K-Dur 20 is priced at 50% of the branded price).

Moreover, the fact that some AB-rated generic drugs reach substitution rates of 80 percent, while other AB-rated generics achieve only 30 percent substitution (*see* Schering's Proposed Finding No. 3.185), indicates that patients, physicians, and pharmacists have the ability to exercise choice when purchasing prescription drugs, even when state generic drug substitution laws provide for automatic generic substitution. Mr. Rosenthal testified that "individual products have different substitution rates," and that the six-month substitution rate for most generics falls within "a broad range from 30 to . . . 80 percent . . . with most products falling into the higher range." Tr. at 8:1541-42 (Rosenthal). A primary reason for the wide range of substitution rates is the different levels of comfort physicians and pharmacists have in prescribing and dispensing drugs based on their therapeutic characteristics and the seriousness of the medical conditions for which they are prescribed.

3.183. Dr. Addanki gave an example of how the mandatory substitution laws offer a misleading indication of monopoly power. Dr. Addanki supposed that there was a mandatory detergent substitution law in Maryland and every time a consumer tried to buy Fab at a Maryland Giant supermarket, the cashier replaced it at the checkout counter with Super G detergent, the

Giant private label. Despite the reduction in sales of Fab and the increase in sale(s) of Super G, that would not make Fab a monopolist. (24 Tr. 5749-50 (Addanki)). It is simply the mandatory substitution law that causes the substitution, not the monopoly power of facts. (24 Tr. 5749 (Addanki)).

Complaint Counsel's Response to Finding No. 3,183:

This finding is misleading and misstates Professor Bresnahan's testimony. Professor Bresnahan's point regarding mandatory substitution laws is that, since there was no AB-rated generic to K-Dur 20 prior to September 2001, K-Dur 20 could not be automatically substituted at the pharmacy level even in states with mandatory substitution laws. He did not testify that the sole fact that an AB-rated generic is substituted for its equivalent branded drug because of a mandatory substitution law means that the branded drug had monopoly power. Rather, he stated that the fact that K-Dur 20 could not be substituted by pharmacists automatically before September 2001, even in states with mandatory substitution laws, was a primary reason why non AB-rated generic potassium chloride supplements could not serve as a competitive constraint on K-Dur 20. Tr. at 3:484 (Bresnahan); CPF 1011. Therapeutic substitution of a non-AB-rated generic would be less cost-efficient than automatic substitution of an AB-rated generic because of the attendant "switching costs." Tr. at 3:490-93 (Bresnahan); CPF 1011-1013.

In addition, the example used by Dr. Addanki is irrelevant, because it involves a market in which there are a number of preexisting products, all of which are competing vigorously with each other and, therefore, none could have monopoly power. Tr. at 6:1186-88 (Bresnahan). This is in contrast to this case, in which there are no preexisting

competitors to K-Dur 20 prior to entry by its generic equivalent. *See* Tr. at 6:1189 (Bresnahan); CPRF 3.187.

3.184. Outside the pharmaceutical industry, the customer is permitted to purchase the brand of his choice or the generic. (24 Tr. 5749 (Addanki)). Under mandatory substitution, however, the AB-rated generic drug's volume increases, and the branded product's volume drops, *because* substitution is required. (24 Tr. 5750 (Addanki)). This does not mean that the branded product is a monopolist, but would mean that each time someone tried to buy the branded product, it was replaced by the generic. (24 Tr. 5750 (Addanki)).

Complaint Counsel's Response to Finding No. 3.184:

This proposed finding is misleading and misstates Professor Bresnahan's testimony to the extent it claims that he automatically defined as a monopolist any branded product that is substituted by an AB-rated generic because of mandatory substitution. *See* CPRF 3.183, 3.182.

3.185. The rate of generic substitution after 6 months of generic competition will range from 30 percent to 80 percent regardless of pioneer drug's prior share. (8 Tr. 1541-42; 1560 (Rosenthal)).

Complaint Counsel's Response to Finding No. 3.185:

The proposed finding is not supported by the evidence cited. While Mr. Rosenthal did say that the rate of generic substitution after 6 months of generic competition will range from 30 percent to 80 percent, he did not say that this occurred

regardless of the pioneer drug's prior share. In fact, he stated the increase in substitution rate is partly related to the high visibility of certain drugs. Tr. at 8:1542 (Rosenthal).

3.186. Reflecting the mandatory substitution laws, sales of K-Dur 20 fell during the fall of 2001. (25 Tr. 6188 (Addanki); CX 1586). Some state substitution laws mandated that a pharmacist could not fill a prescription with K-Dur 20, but instead had to use the generic alternative. (20 Tr. 4824 (Dritsas)). In those states, Schering's earlier efforts doctors to persuade doctors to prescribe K-Dur resulted in sales for the generic, even when the doctor prescribed K-Dur. (6 Tr. 1178 (Bresnahan)). Mandatory substitution laws effectively blocked K-Dur from competing for some patients. (20 Tr. 4824-25 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.186:

Complaint counsel has no specific response.

3.187. Under Professor Bresnahan's test, if a generic under-prices and takes sales away from a brand, the brand would have monopoly power. (6 Tr. 1180-81 (Bresnahan)). But under mandatory substitution laws, AB-rated generics always take sales away from branded products. (6 Tr. 1181 (Bresnahan)). Thus, under the Bresnahan test, all brand name drugs would have monopoly power. But Professor Bresnahan acknowledged that all brand name drugs do not have monopoly power. (*Id.*at 1180).

Complaint Counsel's Response to Finding No. 3.187:

The proposed finding is misleading and misstates Professor Bresnahan's testimony. Professor Bresnahan did not testify that any time a lower priced generic takes

sales away from a branded drug, the branded drug had monopoly power before the generic competitor entered the market. He stated, rather, that whether the branded product had monopoly power prior to the entry of the AB-rated generic would depend on whether "the underpricing and taking sales are . . . substantial in terms of the impact on the marketplace relative to the competitive constraint available from the other products preexisting before" the generic's entry. Tr. at 6:1181 (Bresnahan). This is in contrast to a market where there are preexisting competitors whose competition restrains the pricing of the product whose generic equivalent has entered the market. In that case, one would not expect the generic entrant to have a large impact on the branded product's price or sales because the preexisting firms were already constraining it. Tr. at 6:1182 (Bresnahan). In this case, the fact that K-Dur 20 had monopoly power prior to the entry of Klor Con M20 is supported by the evidence that the preexisting non-AB-rated generics were priced well below the price of K-Dur 20, but did not restrain K-Dur 20's pricing or take sales away from it. *See* CPRF 3.60, 3.81-3.82, 3.169. Moreover, once Upsher launched its AB-rated generic competitor to K-Dur 20, K-Dur 20's sales began to drop drastically (*see* CPRF 3.168), demonstrating that the preexisting products, generic and branded, were not a competitive constraint on K-Dur 20.

c. Higher pricing for a branded product does not indicate monopoly power

3.188. All products in a relevant market do not have to have similar prices. (Addanki 6198). Products compete along different dimensions, and price is only one such dimension. (25

Tr. 6198 (Addanki)). Generics offer a different bundle of attributes from branded products in all sorts of markets, not just pharmaceuticals. (25 Tr. 6198 (Addanki)).

Complaint Counsel's Response to Finding No 3.188:

Complaint counsel has no specific response.

3.189. Generic products are always priced below branded products. (6 Tr. 1179, 1180-81 (Bresnahan)). Generic companies generally have small sales forces, small sales expenses, and only a tiny portion of the research and development expenses of a brand name company. (6 Tr. 1179 (Bresnahan)).

Complaint Counsel's Response to Finding No 3.189:

Complaint counsel has no specific response.

3.190. Charging a higher price does not mean that a branded product has monopoly power, because branded products tend to sell for higher prices than unbranded products. (24 Tr. 5740 (Addanki)). A price difference between Klor Con M10 and K-Dur 10 does not make K-Dur 10 a monopoly. (25 Tr. 6160-61 (Addanki)).

Complaint Counsel's Response to Finding No. 3.190:

Proposed findings 3.190 through 3.195 are incomplete and misleading. They misrepresent Professor Bresnahan's opinion that K-Dur 20 had market power as being based solely on whether a branded product is priced higher than its generic equivalent. In fact, Professor Bresnahan's conclusion that K-Dur 20 had monopoly power is based on a number of considerations, including: (1) the almost insignificant levels of generic

substitution for K-Dur 20 prior to September 2001, compared with the extremely large and rapid substitution of the AB-rated generic Klor Con M20 that were predicted by respondents, and actually occurred, after Klor Con M20's entry in September 2001 (*see* Tr. at 3:430, 3:439-40, 3:3:470-473, 3:480-81, 3:484, 34:8038-39 (Bresnahan); CPF 988-993, 996-1036); (2) the inability of other potassium chloride products to restrain K-Dur 20 competitively, as demonstrated by its annual price, sales, and profit increases in the face of generics priced at a fraction of K-Dur 20's price (*see* Tr. at 3:431-32, 3:475-76, 3:479-81, 3:483, 4:729-31, 5:851-52, 6:1227-30 (Bresnahan); CPF 972-983); and (3) the perceptions of payers, physicians, and patients that other potassium chloride supplements were not good substitutes for K-Dur 20. *See* Tr. at 3:478, 3:484, 6:1173 (Bresnahan); CPF 1024-1037,1069-1070, 1119-1123.

3.191. The higher prices for the brand products reflect the promotion of the brands. (24 Tr. 5751 (Addanki)). Judge Richard Posner, Chief Judge of the United States Court of Appeals for the Seventh Circuit, (6 Tr. 1151 (Bresnahan)), explains in his book, Economic Analysis of Law, that price differences between a brand-name bleach and a house-brand bleach can be explained by the difference in marketing costs and do not necessarily indicate the existence of monopoly power. (34 Tr. 8206-07 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.191:

Proposed findings 3.190 through 3.195 are incomplete and misleading, in that they misrepresent Professor Bresnahan's opinion that K-Dur 20 had market power as being based solely on whether a branded product is priced higher than its generic

equivalent. *See* CPRF 3.190.

This proposed finding also is incomplete and misleading, in that it neglects to mention that higher prices for a brand product can also be due to that product's market power. The ability of K-Dur 20 to charge and maintain a 100 percent (or more) price premium over generic potassium chloride products throughout the 1990s and 2000, and the inability of other potassium chloride products to restrain K-Dur 20 competitively, as demonstrated by its annual price, sales, and profit increases in the face of generics priced at a fraction of K-Dur 20's price, is strong evidence of K-Dur 20's market power. *See* Tr. at 3:431-32, 3:475-76, 3:479-81, 3:483, 4:729-31, 5:851-52, 6:1227-30 (Bresnahan).

3.192. Premiums to a brand are ubiquitous. (24 Tr. 5735 (Addanki)). For example, branded bread will sell at a higher price than private label bread that has the same quality, because consumers are willing to pay for the brand. (24 Tr. 5736 (Addanki)).

Complaint Counsel's Response to Finding No. 3.192:

Proposed findings 3.190 through 3.195 are incomplete and misleading, in that they misrepresent Professor Bresnahan's opinion that K-Dur 20 had market power as being based solely on whether a branded product is priced higher than its generic equivalent. *See* CPRF 3.190.

3.193. Economists do not view branding as evidence of monopoly; they view branding activity as a form of investment. (24 Tr. 5736 (Addanki)). A company invests in building its brand, and the premium in the form of higher prices is the return to that investment. (24 Tr. 5736 (Addanki)). Branding is a dimension of competition and is generally pro-competitive. (24 Tr.

5736 (Addanki)).

Complaint Counsel's Response to Finding No. 3.193:

Proposed findings 3.190 through 3.195 are incomplete and misleading, in that they misrepresent Professor Bresnahan's opinion that K-Dur 20 had market power as being based solely on whether a branded product is priced higher than its generic equivalent. *See* CPRF 3.190.

This proposed finding also is incomplete and misleading, in that it neglects to mention that higher prices for a brand product can also be due to that product's market power. The ability of K-Dur 20 to charge and maintain a 100 percent (or more) price premium over generic potassium chloride products throughout the 1990s and 2000, and the inability of other potassium chloride products to restrain K-Dur 20 competitively, as demonstrated by its annual price, sales, and profit increases in the face of generics priced at a fraction of K-Dur 20's price, is strong evidence of K-Dur 20's market power. *See* Tr. at 3:431-32, 3:475-76, 3:479-81, 3:483, 4:729-31, 5:851-52, 6:1227-30 (Bresnahan).

3.194. Pricing in the pharmaceutical context does not follow the pattern in other industries. It is generally expected that the introduction of a lower-priced competitor will cause the prices of higher-priced products to fall. (6 Tr. 1195 (Bresnahan)). But in the pharmaceutical industry, entry of a lower-priced generic does not cause the price of the brand name product to fall. (6 Tr. 1194-95 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.194:

Proposed findings 3.190 through 3.195 are incomplete and misleading, in that

they misrepresent Professor Bresnahan's opinion that K-Dur 20 had market power as being based solely on whether a branded product is priced higher than its generic equivalent. *See* CPRF 3.190.

This proposed finding also is incomplete and misleading, in that it omits the fact that, although the price of the product that bears the brand name may not fall after generic entry, the manufacturer of the branded product may choose to sell the branded product under a generic label, in order to compete with the generic entrants, thereby effectively reducing the price of the branded product. In this case, Schering's marketing plans assume that Schering could still sell K-Dur 20 profitably, even after effectively reducing the price by 50 percent, by selling it as a generic product through Schering's generic arm, Warrick. *See, e.g.,* CX 144 at SP 22 00001-05; [redacted]; *see also* Tr. at 25:5965-80 (Addanki) (Schering forecasts assumed that generics of K-Dur 20 would enter the market at about 50% of the price of K-Dur 20 and capture 50% of the market, and that Warrick would win back 50% of the generic sales). Thus, Schering planned to effectively reduce the price of K-Dur 20 by 50 percent to compete with entry by an AB-rated generic. The fact that Schering made such plans only under threat of entry by an AB-rated generic, and not before, in response to the lower pricing of other potassium chloride supplements, suggests strongly that K-Dur 20's pricing before entry by Klor Con M20 was supracompetitive.

3.195. Professor Bresnahan conceded that a 66% price difference between branded Bayer

aspirin and generic CVS aspirin would not establish in and of itself that Bayer has market power. (5 Tr. 1001-02 (Bresnahan)). Thus, Professor Bresnahan conceded that the difference in price between a brand name pharmaceutical and a generic alone also need not connote monopoly power. (34 Tr. 8207 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.195:

Proposed findings 3.190 through 3.195 are incomplete and misleading, in that they misrepresent Professor Bresnahan's opinion that K-Dur 20 had market power as being based solely on whether a branded product is priced higher than its generic equivalent. *See* CPRF 3.190.

d. Pricing above marginal costs is an improper test

3.196. Professor Bresnahan conceded that "pricing above marginal cost in a differentiated industry does not establish any inefficiency once the need to cover the fixed costs of product design are taken into account." (6 Tr. 1194 (Bresnahan)). K-Dur is in a product-differentiated industry. (6 Tr. 1194 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.196:

The proposed finding is incomplete and misleading, in that it quotes Schering's counsel, rather than Professor Bresnahan, who actually testified that "it depends on what you mean by 'taken into account,' but I agree. Prices above marginal cost in a product-differentiated industry are not necessarily inefficient." Tr. at 6:1194 (Bresnahan).

3.197. Professor Bresnahan could not cite a single example of a brand that charges a

price equal to marginal cost. (6 Tr. 1185 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.197:

The proposed finding is not supported by the cited testimony. Professor Bresnahan was asked whether he was aware of a single therapeutic category in which competing products competed the price down to the generic level when to do so made it impossible for them to cover their R & D costs, their marketing costs and their costs of production. Professor Bresnahan replied, "No." Tr. at 6:1185 (Bresnahan).

3.198. If pricing above cost were the test, Upsher would also be a monopolist because Upsher's margins on wax matrix Klor-Con 10 were well above cost. In the early 1990s, Upsher's gross margins were over 80%; its product margins were 40-60%. (CX 267 at SP 23 00214). Upsher Smith's "product margins" for the 8 and 10 mEq Klor Con in 1995 and 1996 were 75.6 percent and 74.2 percent, respectively, and projected to remain above 74.5 percent from 1997-1999. (CX 234 at USL 12787; CX 254 at USL 05261).

Complaint Counsel's Response to Finding No. 3.198:

The proposed finding is irrelevant because Upsher's monopoly power or lack thereof in Klor-Con 10 has no bearing on Schering's monopoly power in K-Dur 20. The proposed finding is contradicted by other evidence. The proposed finding attempts to infer monopoly power from accounting data, which is an unreliable method. Tr. at 6:1193 (Bresnahan) (inferring market power from accounting data is a bad idea).

e. K-Dur 20's price was competitive

3.199. Finally, Professor Bresnahan ignores that K-Dur 20 was "priced competitively." (CX 740). (20 Tr. 4690 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.199:

This proposed finding is false. Professor Bresnahan did not ignore that K-Dur 20 was "priced competitively", he explained in what sense it was priced competitively. Professor Bresnahan explained that an entity with market power, such as Schering had with K-Dur 20 would raise the price of that product until there was some substitution between the monopoly product and its nearest, albeit imperfect substitutes. At that price level, the monopoly product would appear to be competitive with the substitute products. On average, Schering charged more for its K-Dur 20 than other potassium chloride products. K-Dur 20's share of total sales revenues of potassium chloride products compared to K-Dur 20's share of total prescription for potassium chloride demonstrate that its price is higher, because its share of revenues is substantially higher than its share of prescriptions. *See* CPF 979-983. Schering was exercising market power with K-Dur because it was raising its relative prices yearly while increasing its share of sales. In such circumstances, Professor Bresnahan explained that K-Dur would appear to be priced competitive to other potassium chloride products because there would be some substitution. But Professor Bresnahan went on to explain that such apparent competition did not mean that K-Dur 20 and the apparently competitive products were in the same product market. To so conclude would be to fall into the cellophane trap or cellophane fallacy. It is the exercise of market power that makes the two products appear to be

competitive so it would be a fallacy to conclude that because of that apparent competition that the monopoly product did not have market power.

3.200. K-Dur 20 is priced competitively with other branded potassium chloride supplements. K-Dur 20 did not enjoy a premium price as compared with other brands of potassium chloride. (4 Tr. 730 (Bresnahan)). In fact, some branded products were priced higher than K-Dur 20, and some were priced lower. (24 Tr. 5741 (Addanki); SPX 2069) (demonstrative).

Complaint Counsel's Response to Finding No. 3.200:

The finding misrepresents the substance of the testimony of Professor Bresnahan. In the cited testimony, Professor Bresnahan is being cross-examined on one of the respondents documents. While it is literally true that for at least some brands of potassium chloride products, the document shows that K-Dur 20 was not priced higher, the document also states that generic potassium chloride products were priced thirty percent less than the price of K-Dur 20. K-Dur could maintain a price differential of thirty percent above generic potassium chloride products and still increase its share of total potassium chloride sales, the other branded products could not. While K-Dur 20's share of sales of all potassium chloride products, whether measured in dollar sales or prescriptions, increased from 1996 through 2000, the other brands lost share of sales. The fact that other brands attempted to charge high prices as Schering did for K-Dur 20 does not prove that the other brands were in the same antitrust market as K-Dur 20. The

fact that Schering succeeded with K-Dur 20 in increasing price while also increasing share of total sales, while the other producers lost their customers to generic potassium chloride products when they attempted to charge high prices shows that K-Dur 20 and the other potassium chloride brands of 8 and 10 mEq products are not in the same antitrust market.

3.201. A review of the prices charged for potassium chloride supplements revealed that there were products priced lower than K-Dur 20 and products priced higher than K-Dur 20, for a 20 mEq dose. (24 Tr. 5741 (Addanki); SPX 2069) (demonstrative). According to IMS data, the highest priced potassium chloride product in 1997, for a 20mEq dose, was K-Tab 10. (SPX 2071 (demonstrative); 24 Tr. 5742 (Addanki)). Under the Bresnahan analysis, K-Tab 10 would have a monopoly, but it does not have a monopoly in any sense. (24 Tr. 5742 (Addanki)).

Complaint Counsel's Response to Finding No. 3.201:

The finding is not supported by the cited testimony. No where in the testimony cited does Addanki state that under Professor Bresnahan's analysis K-Tab 10 would have monopoly power.

The finding is also incomplete and misleading to the extent that it implies that Professor Bresnahan's analysis equated of high prices alone with monopoly power. Professor Bresnahan looked at a product's prices and whether competitive products constrained that products pricing. Professor Bresnahan's conclusion was that the existing potassium chloride products did not prevent Schering from exercising market power in

the pricing of K-Dur 20. However the same cannot be said for the other high priced , branded potassium chloride products who lost market share to generic products throughout the late 1990's. CPF 979-983. Using this analysis one would conclude that K-Tab did not have a monopoly, because although K-Tab was sold for high prices, its declining share of total sales indicates that it did face substantial competition form other 8 and 10 mEq potassium chloride products and lost its share of sales to lower priced products, the antithesis of a monopolists ability to profitably charge high prices, i.e. to they charged high prices, i.e. to maintain or increase sales when increasing prices as Schering did with K-Dur 20..

3.202. Similarly, several brands with smaller shares than K-Dur 20 were raising price faster than Schering. (25 Tr. 6203-04 (Addanki)). Micro-K raised its price 61 percent in the 8 mEq dosage and 78 percent in the 10 mEq dosage, but that does not indicate that it is a monopoly. (25 Tr. 6204 (Addanki)). Ethex 10 raised its price 54 percent, but is not a monopoly. (25 Tr. 6204 (Addanki)). These products compete with each other, as well as other oral potassium chloride supplements, in the same product market.

Complaint Counsel's Response to Finding No. 3.202:

The proposed finding is incomplete and therefor misleading. The high priced 8 and 10 mEq potassium chloride products saw their small share of total potassium chloride sales stagnate or decline. CPF 979-983. These products had many prescriptions written for them filled with generic potassium chloride. CPF 952. They certainly faced

competition from other oral potassium chloride products. However, K-Dur 20 saw its prices go up every year while its share of sales of all potassium chloride products increased wether measured by dollar sales or share of total prescriptions. CPF 972-983. Virtually no K-Dur 20 prescriptions were filled by generic products until September 1, 2001 when Upsher introduced its generic 20 mEq potassium chloride that was AB rated to D-Dur 20 onto the market. Schering control of its prices showed that it had market power, the erosion of the other brands sales when they attempted to maintain high prices showed that they had little if any market power.

3.203. According to Merck-Medco's 2001 formulary, the cost of K-Dur 20 was roughly equivalent to the cost of other powdered, tablet and capsule potassium chloride products. (2 Tr. 215,217-18,224 (Teagarden); CX 56 at Merck-Medco 000197; CX 57; USX 131); (Dritsas 4818-19); USX 837).

Complaint Counsel's Response to Finding No. 3.203:

The proposed finding is incomplete and therefor misleading. *See* CPRF 3.202.

3.204. Schering could not raise K-Dur 20's price above the price of the competition. Despite Schering's significant monetary commitment to marketing and promotion of K-Dur 20, in 1997 K-Dur 20's price was approximately the same as other branded potassium chloride products. (15 Tr. 3426 (Russo)).

Complaint Counsel's Response to Finding No. 3.204:

The finding is incomplete and misleading. Part of the finding is not supported by the facts. On average, Schering could and did raise its price above other potassium chloride products. This is demonstrated by the fact that K-Dur 20 had a much higher share of total potassium chloride sales revenue than share of total prescriptions. With respect to the comparison between the price of K-Dur and the price of other branded potassium chloride products, the Schering was able to increase its share of sales while increasing its price, other brands saw their share of sales stagnate at low levels or fall over time when they charged high prices. CPF 972-983.

3.205. Schering felt competitive pressure from the other potassium chloride products and felt constrained in its ability to price because of the competition. (24 Tr. 5714 (Addanki)). Thus, in determining the price of K-Dur 20, Schering considered "competitive 8/10 mEq products". (25 Tr. 5958 (Addanki); SPX 954). K-Dur had to be competitive with generic products. (24 Tr. 5714 (Addanki)).

Complaint Counsel's Response to Finding No. 3.205:

The finding is incomplete and misleading. Even a monopolist will recognize competitors when price at supra-competitive levels. This is the essence of the Cellophane Fallacy. Professor Bresnahan directly addressed the logical flaw demonstrated in the finding.

Q. Now -- and how does Dr. Addanki's -- and are you familiar with Dr.

Addanki's testimony relating to the pricing constraints Schering experienced in the period 1997 to -- prior to generic entry?

A. Yes.

Q. What's your understanding of that testimony?

A. That their pricing was constrained to the competitive level by this competition.

Q. And do you have an understanding of what his view was of their ability to raise prices even more?

A. Yes, he believes that because -- that they would not be able to raise price even more and concludes from that that they would not be -- that they are not a monopolist.

Q. How does that analysis compare to the cellophane fallacy?

A. That's a -- that's a cellophane fallacy mistake. In the -- it's -- a monopolist won't be able to profitably further raise its price if it's raised its price -- if it raises its price to the level where it faces some competition, it -- a monopolist should, of course, think, I can't raise my price any more. So, that evidence alone isn't evidence against monopoly.

Tr. at 34:8019-20 (Bresnahan).

The existence of similarly priced potassium supplements does not alter the facts that 1) Schering was able to raise the price of K-Dur 20 without losing sales (CPF 972-987); 2) generic K-Dur 20 was forecasted, and did take, substantial sales from K-Dur 20 at a substantial discount (CPF 952-971, 988-992); 3) only generic K-Dur 20 was

forecasted, and did, force Schering to lower the price of its 20 mEq potassium supplement by launching its own generic K-Dur 20 (CPF 993-1036).

3.206. K-Dur 20's competitors had a depressing effect on K-Dur's pricing. (15 Tr. 3416 (Russo)). As a result of competition from low-priced products, Schering was forced to price K-Dur competitively and could not aggressively price K-Dur. (15 Tr. 3416, 3527 (Russo)). Although Schering annually raised the price of both K-Dur 20 and K-Dur 10, the increase was no greater than the rate of inflation. (15 Tr. 3471-72, 3526 (Russo)).

Complaint Counsel's Response to Finding No. 3.206:

The finding is incomplete and misleading. *See* CPRF 3.205.

3.207. Professor Bresnahan conceded that generics put pricing pressure on K-Dur 20 and other branded products. (4 Tr. 712-13 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.207:

The finding is incomplete and misleading. The cited testimony states that the "rate of branded prescribing ... will come under pressure as managed care organizations increase control over physicians." and that this pressure was not coming from Klor Con M20 which did not exist at the time. Tr. at 4:712 (Bresnahan). Thus, Schering's inability to "aggressively price K-Dur" does not alter the facts that 1) Schering was able to raise the price of K-Dur 20 without losing sales (CPF 972-987); 2) generic K-Dur 20 was

forecasted, and did take, substantial sales from K-Dur 20 at a substantial discount (CPF 952-971, 988-992); 3) only generic K-Dur 20 was forecasted, and did, force Schering to lower the price of its 20 mEq potassium supplement by launching its own generic K-Dur 20 (CPF 993-1036).

3.208. Schering's focus on prices charged for other potassium chloride supplements is not surprising. Prior to September 2001, potassium chloride supplements were available from many suppliers at a wide range of prices. Price discounting from published IMS or Redbook "Average Wholesale Prices" ("AWP") was also common. (CX 143 at SP 26 00003-00004). For example, in mid 1999 IMS reported the AWP and "Wholesale Acquisition Cost" ("WAC") for 27 potassium chloride supplements. (USX 656 at USL 18221-223) Based upon a 20 mEq dose, tablet and capsule unit WAC vary from $0.099 (K-10) to $0.7172 (K-Tab 10). The WAC for K-Dur 20 was $0.4165. (USX 656 at USL 18221). For powders, the 20 mEq dose cost ranges from $0.1119 (Klor Con 20 mEq) to $1.0649 (K-Lor 20 mEq). The WAC for effervescent tablets are $0.1286 (Klor Con 25 mEq) to $0.8334 (K-Lyte 25 mEq) for a 20 mEq dose. Six tablet/capsule products had a WAC higher than K-Dur 20 for a 20 mEq dose: K-Dur 10, Micro K8, Kaon CL 8, Slow K 8, Klotrix 10, and K-Tab 10. (USX 656 at USL 18221-23).

Complaint Counsel's Response to Finding No. 3.208:

The finding is irrelevant. The existence of similarly priced potassium supplements does not alter the facts that 1) Schering was able to raise the price of K-Dur 20 without losing sales (CPF 972-987); 2) generic K-Dur 20 was forecasted, and did take,

substantial sales from K-Dur 20 at a substantial discount (CPF 952-971, 988-992); 3) only generic K-Dur 20 was forecasted, and did, force Schering to lower the price of its 20 mEq potassium supplement by launching its own generic K-Dur 20 (CPF 993-1036). *See* CPRF 3.199, 3.202.

3.209. Upsher's documents show that in the "10/20 mEq market, the focus has been on price with continued growth from generics such as Ethex and new entries from Apothecon, ESI Lederle, Medeva and Biocraft in 1996. The major brands have started to trade price for volume to compete with strong generic competition." (CX 19 at USL 15228; 25 Tr. 6192 (Addanki)). This reflects that there was a lot of competition among everyone in the market. (25 Tr. 6192 (Addanki)).

Complaint Counsel's Response to Finding No. 3.209:

The finding is contradicted by other evidence. The price of K-Dur 20 increased relative to the price of generic products while K-Dur 20 sales continued to increase. CPRF 3.204.

3.210. In part, managed care and generic competition were constraining Schering's prices: "The current high rate of branded prescribing in the potassium market will come under increasing pressure as managed care organizations and states increase control over physician prescribing." (CX 13 at SP00 3044); 4 Tr. 708-09 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.210:

The finding is further evidence that Schering possessed monopoly power through K-Dur 20. The fact that one segment of consumers received lower prices for K-Dur 20 is evidence of price discrimination. Absent evidence of different costs associated with a particular consumer, charging different consumers different prices is price discrimination. The ability to price discriminate can only occur in the presence of market power. *See* Tr. at 34:8027-8031 (Bresnahan). Respondent's experts provided no analysis to determine if the reduced priced charged to certain customers was price discrimination arising from market power. Likewise, no evidence was put forward to show that the reduced priced charged to certain customers resulted from differences in cost.

3.211. Indeed, the generic substitution rate has significantly increased in recent years, in part because of the push by managed care organizations to encourage generic usage. (8 Tr. 1542 (Rosenthal)).

Complaint Counsel's Response to Finding No. 3.211:

The finding is incomplete. Substitution rates of K-Dur 20 prior to entry of generic K-Dur 20 among manage care organizations was minimal. CPF 1030. Substitution rates for other branded products was very significant. CPF 952; 1030-36

3.212. In response, Schering's pricing focused particularly on HMOs, especially staff

HMOs, as being at the leading edge of influencing prescribing behavior. (24 Tr. 5715 (Addanki)). In one instance, Kaiser, a staff model HMO, demanded drastic price reductions from Schering if it wanted K-Dur 20 to be covered by Kaiser. (24 Tr. 5716 (Addanki)). Schering had no choice but to oblige or face substitution by a generic. (24 Tr. 5716 (Addanki)). As one Schering document reported, "In some markets, primarily staff HMOs, K-Dur 20 utilization is limited/challenged by low cost 10mEq generic alternatives." (CX 13 at SP 003044; 4 Tr. 709 (Bresnahan).

Complaint Counsel's Response to Finding No. 3.212:

The finding is further evidence that Schering possessed monopoly power through K-Dur 20. The fact that staff model HMO's could receive lower prices for K-Dur 20 is evidence of price discrimination. Absent evidence of different costs associated with staff model HMO's, charging staff model HMO's different prices than charged to other customers is price discrimination. The ability to price discriminate can only occur in the presence of market power. *See* Tr. at 34:8027-8031 (Bresnahan). Respondent's experts provided no analysis to determine if the reduced priced charged to certain customers was price discrimination arising from market power. Likewise, no evidence was put forward to show that the reduced priced charged to certain customers resulted from differences in cost.

3.213. In an agreement with Medco, a pharmacy benefit manager, Schering discounted its K-Dur products. (2 Tr. 226 (Teagarden); USX 131at Merck-Medco 000206). Upsher offered

a contract with favorable terms to Merck-Medco to buy its Klor Con M20 and M10. (20 Tr. 4818-19 (Dritsas); USX 837). Merck-Medco rejected the offer, because it has a "more favorable" situation with Schering for its K-Dur 20 product. (20 Tr. 4819 (Dritsas)).

Complaint Counsel's Response to Finding No. 3,213:

The proposed finding is irrelevant, because the products Upsher was attempting to place on the Merck-Medco formulary were Klor Con M20 and M10, the AB-rated generic equivalents of K-Dur 20 and K-Dur 10, respectively. There is no issue in this case as to whether K-Dur 20 competed with Klor Con M20 – it did. Therefore, the assertion that Schering's K-Dur products competed with Upsher's Klor Con M products for the Merck-Medco account is irrelevant.

The finding is further evidence that Schering possessed monopoly power through K-Dur 20. The fact that Merck-Medco obtained K-Dur 20 at a reduced price in comparison to other customers is evidence of price discrimination. Absent evidence of different costs associated with a particular consumer, charging different consumers different prices is price discrimination. The ability to price discriminate can only occur in the presence of market power. *See* Tr. at 34:8027-8031 (Bresnahan).

The proposed finding also is incomplete and misleading, in that it is not clear to what degree Schering discounted K-Dur's price to Medco (later Merck-Medco). The document used during Mr. Teagarden's cross examination (USX131) contained a reference to a "market share rebate percentage." However, the document was redacted and did not show the amount of the rebate percentage. Tr. at 2:226 (Teagarden).

Moreover, empirical evidence indicates that Schering's rebates on K-Dur 20 did not bring the price of K-Dur 20 anywhere near a competitive level with respect to the preexisting generic products. *See* CPRF 3.214.

3.214. When Upsher talked to Schering customers, Upsher discovered that in many segments, Schering was pricing K-Dur 20 like a generic. (20 Tr. 4905 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.214:

This proposed finding is unsupported by evidence. Upsher employees testified what customers told them over the hearsay objections of complaint counsel and the evidence was admitted but not for the truth of the matter stated. Therefore claims that customers told Upsher that Schering was charging low prices cannot be used to prove that Schering was charging low prices. Schering's share of total potassium chloride dollar sales compared to Schering's share of total potassium chloride prescriptions shows that Schering was on average charging higher prices than other potassium chloride producers.

If Schering was charging low prices at some customers and higher prices elsewhere, the finding is further evidence that Schering possessed monopoly power through K-Dur 20. The fact that some segments of customers obtained K-Dur 20 at a reduced price. Absent evidence of different costs associated with a particular consumer, charging different consumers different prices is price discrimination. The ability to price discriminate can only occur in the presence of market power. *See* Tr. at 34:8027-8031 (Bresnahan).

3.215. In late 2000/early 2001, one wholesaler, Bergen, indicated to Upsher that Schering is a company that "deal[s] in many ways like a generic company" with respect to its willingness to compete on price. (20 Tr. 4670-72 (Dritsas)). Several other companies conveyed the same information about Schering to Upsher, including McKesson. (20 Tr. 4673 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.215:

The finding is based on unreliable hearsay and may not be used to establish Schering's pricing policies. Further, the finding does not specifically address the product at issue in this case and is therefore irrelevant. *See* CPRF 3.214.

3.216. Upsher recognized that K-Dur 20 was "priced competitively." (20 Tr. 4690 (Dritsas); CX 740). In 1996, Upsher Smith reviewed the pricing of four competitors, including Abbott, Summitt, Robins and Key/Schering. The products Upsher Smith included were (1) K-Tab (Abbott), (2) Ten K (Summit), (3) Micro K 10 (Robins), and (4) K-Dur 20 and K-Dur 10 (Key/Schering). USX 422 at FTC 1002260-2261. Upsher described Key/Schering's pricing as "competitive," noting that K-Dur's AWP price was lower than K-Tab. (USX 422 at FTC 1002261).

Complaint Counsel's Response to Finding No. 3.216:

The proposed finding is irrelevant. As Professor Bresnahan testified, it is not enough to look merely at the prices of other products – one must also consider factors such as their sales volume in order to determine their competitive significance. Tr. at 34:8031-33 (Bresnahan); CPF 1108. During the late 1990s, the sales of the other branded

potassium chloride products were small relative to K-Dur 20, and those sales were declining. Tr. at 34:8033-35 (Bresnahan); CPF 1108. In addition, at various times during this period, the prices of certain other branded products fell relative to K-Dur 20, effectively creating a price cut relative to K-Dur 20. CPF 1108. Moreover, the price of K-Dur 20 relative to Klor Con 10 and Klor Con 8 rose during this period. Tr. at 34:8035-36. However, instead of either reducing its price to compete with these products or losing sales to them, K-Dur's sales and prices kept rising over this period. Tr. at 34:8035-37 (Bresnahan); CPF 1108. This is strong evidence that these other products were "not putting an important constraint on K-Dur [20]" (Tr. at 34:8034-35 (Bresnahan)), and is evidence for, rather than against, K-Dur 20's market power. Tr. at 34:8037-38 (Bresnahan).

3. Price Discrimination

3.217. Professor Bresnahan also suggests that price discrimination in the potassium chloride supplement market may suggest monopoly power. But Professor Bresnahan did not study whether there was price discrimination in the oral potassium chloride supplement market. (34 Tr. 8021 (Bresnahan); 24 Tr. 5755 (Addanki); 25 Tr. 6193 (Addanki)).

Complaint Counsel's Response to Finding No. 3.217:

The proposed finding is irrelevant. Professor Bresnahan's testimony regarding price discrimination was in rebuttal of Dr. Addanki's claim that evidence of price discrimination is irrelevant to a determination of market power. Specifically, he pointed

out that Dr. Addanki's opinion is contrary to the prevailing economic view, and that examples used by Dr. Addanki to illustrate price discrimination were ambiguous in that, on their face, they could have represented merely price dispersion, rather than price discrimination. *See* CPF 1092-1094.

3.218. Price discrimination has no bearing on monopoly power. (24 Tr. 5755 (Addanki)). Price discrimination is pervasive and does not imply any competitive problem. (34 Tr. 8199 (Bresnahan). Price discrimination simply means that customers are charged different prices for the same product, and it is widespread in the economy. Examples include: senior citizen discounts at movie theaters; early bird specials at restaurants; and varying airfares for the same flight; (24 Tr. 5756 (Addanki); 25 Tr. 6165 (Addanki)); and coupons in the supermarket. (34 Tr. 8199 (Bresnahan)). This does not make movie theaters, restaurants, or airlines monopolists. (24 Tr. 6165 (Addanki)). Judge Posner has explained that in cases like those, where there are joint and common costs, differing price-cost margins do not imply monopoly power. (34 Tr. 8204-06 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.218:

The proposed finding is contradicted by other evidence. As Professor Bresnahan explained, price discrimination is evidence of monopoly power. Tr. at 34:8021 (Bresnahan). Professor Bresnahan also explained that the examples relied upon by Dr. Addanki do not support Dr. Addanki's opinion. CPF 1092-1094. Dr. Addanki's examples of charging different prices for different products that appear to be the same products. So, for an earlier bird special, if the restaurant has higher costs of service at the

peak time, it might charge a lower price to customers that eat earlier when the restaurant has lower cost of service. Tr. at 34:8030 (Bresnahan). That would be an example of price dispersion not price discrimination. Tr. at 34:8200 (Bresnahan) (senior citizen discount at a movie theater).

The finding is misleading in its reliance on the quote from Posner. Posner was distinguishing between price discrimination and charging different prices to different customers: "Where there are joint or common costs, prices to different customers may be proportioned differently to the marginal costs of serving each customers without being discriminatory in the sense relevant to inferring monopoly." Tr. at 34:8202 (Bresnahan). The quote says that charging different prices for different products that share common costs is not evidence of monopoly power. Tr. at 34:8202-03 (Bresnahan).

Dr. Addanki's opinion that price discrimination has no bearing on monopoly is wrong and contradicts basic economic learning. Judge Posner on in the same book wrote: "Persistent discrimination is very good evidence of monopoly because it is inconsistent with a competitive market; it implies that some consumers are paying more than the costs of serving them, a situation that would disappear with competition." Tr. at 34:8239 (Bresnahan). In "Predatory Systems Rivalry: A Reply," Professor Willig wrote, "It is clear that the opportunity to price discrimination also requires monopoly power." Tr. at 25:6035 (Addanki).

Scherer And Ross's *Industrial Organization and Economic Performance*, a widely used textbook on industrial organization states (on page 489) "For a seller to practice price discrimination profitably, three conditions must satisfied. First, the seller

must have some control over price – some monopoly power." Tr. at 34:8027-28 (Bresnahan); *see also* CX 752 (demonstrative illustrating testimony).

The "Price Discrimination" chapter of *The Handbook of Industrial Organization* states (on page 599) "Three conditions are necessary in order for price discrimination to be a viable solution to a firm's pricing problem. First, the firm must have some market power." Tr. at 34:8029 (Bresnahan). The handbook is the "compendia of recent research and methodologies in economics" and is "written to bring graduate students up to the frontier." Tr. at 34:8028 (Bresnahan).

Dr. Addanki's incorrect opinion on the relationship between monopoly power and price discrimination makes his opinion on market definition unreliable. Dr. Addanki relies on the fact that Schering reduce prices to some customers has evidence that disproves market power. If Schering's reducing price is price discrimination, however, the fact contradicts Dr. Addanki's opinion. Instead of determining whether Schering was price discriminating, Dr. Addanki relied on incorrect economic analysis – that price discrimination has nothing to do with market power. Tr. at 34:8030-31 (Bresnahan). Therefore, Dr. Addanki's conclusion that Schering lacked monopoly power rests on incorrect legal analysis.

4. The K-Dur patent

3.219. Professor Bresnahan concedes that the fact that a product is covered by a patent does not necessarily mean that the product has monopoly power. (6 Tr. 1167-68 (Bresnahan); 27 Tr. 6568 (Kerr)).

Complaint Counsel's Response to Finding No.3.219:

This proposed finding is irrelevant. Professor Bresnahan's answer was given in the context of a general question concerning whether one can necessarily infer market power from patent protection, without reference to this case or any more specific context. Tr. at 6:1167-68 (Bresnahan). In contrast, Dr. Kerr acknowledged:

> The first prong of Complaint Counsel's test asks whether the pioneer has market power. While this would seem to be a reasonable question, in the context it is proposed, it is not. it can have only one answer. If a pioneer's patent did not provide any market power, there would be no reason for a generic to challenge the patent.

Tr. at 27:6571 (Kerr).

II. THE EFFECT OF NET CONSIDERATION

A. The Bresnahan Test

3.220. Professor Bresnahan's three-part test for determining whether a patent settlement between a branded pharmaceutical firm and a potential generic entrant is anti-competitive made its very first appearance in Professor Bresnahan's August 2001 report (4 Tr. 645, 658 (Bresnahan)). He has not tested it empirically. Professor Bresnahan has not examined any settlement agreements involving payments to the potential entrant to determine whether the settlement agreement proved more or less competition as litigating. (6 Tr. 1145-46 (Bresnahan)). Complaint counsel's expert, Max Bazerman, conceded that "there is a large body of behavioral decision research showing that individuals involved in negotiation often deviate from the economic model of rationality." (36 Tr. 8604 (Bazerman)). That is true of "expert as well as of "naïve" negotiators. (36 Tr. 8604 (Bazerman)).

Complaint Counsel's Response to Finding No. 3.220:

The proposed finding is incomplete and misleading. Professor Bresnahan's three-part test comes from well-established economic principles that are applicable across industries and in different contexts. CPF 1129 - 1133. While Professor Bazerman did explain that there is a body of research showing that judgment in negotiations frequently deviates from rational models, when asked whether he saw anything in this literature that would lead him to a conclusion that Schering's $60 million payment to Upsher was not for delay, he replied that he did not. Tr. at 36:8504 (Bazerman).

3.221. The third prong of the Bresnahan test, which infers delay merely from the

existence of a payment to the potential entrant, addresses a novel subject in the field of economics. (29 Tr. 7232 (Willig)). Although there is a long history of economics dealing with competitive effects, there is no developed economic theory that deals with patent settlement agreements involving net consideration. (26 Tr. 6347 (Kerr)). Economists have been looking at this kind of issue for only a short time and should show some humility on this subject. (29 Tr. 7231-32 (Willig)).

Complaint Counsel's Response to Finding No. 3.221:

The proposed finding is incomplete and misleading. The third prong of the test criteria that Professor Bresnahan used was not merely the existence of a payment to the potential entrant, but rather the existence of a payment for the potential entrant to delay its entry. CPF 1129. In his analysis of the purpose of the $60 million payment from Schering to Upsher, Professor Bresnahan examined the available evidence to identify justifications other than delay. He "looked for other justifications in what the managers said but didn't find them." Tr. at 4:608 (Bresnahan). Professor Bresnahan's conclusion that the payment for delay was based on (1) analysis of the parties' incentives, (2) evidence that the parties acted on their incentives, and (3) evidence that the $60 million payment was not for Niacor-SR or the other licensed products. CPF 1185 - 1208. The proposed finding is contrary to more reliable evidence. Delaying uncertain competition harms consumers. CPF 1166-72. The cause of the uncertainty does not matter. CPF 1171-72; 1338-44. Therefore, the standard definition of an anti-competitive contract applies to analyzing whether a patent settlement harms competition. Tr. at 3:418-19 (Bresnahan). The approach would be the same for settlement contracts across

industries, including the automobile industry, the construction industry, or the computer industry. Tr. at 4:639 (Bresnahan).

3.222. Economists have not had enough experience to draft guidelines concerning the impact of net consideration. (25 Tr. 6155-56 (Addanki), 29 Tr. 7231-32 (Willig)). Nor have the courts and the agencies had empirical experience applying the third prong of the Bresnahan test. (Bresnahan 1028).

Complaint Counsel's Response to Finding No. 3.222:

The proposed finding is incomplete and not supported by the evidence. In the cited portion of the transcript, Dr. Addanki testified that economists probably did not have enough experience with the conduct to draft guidelines for businessmen to apply in their patent negotiations. He did not testify that economists do not have enough experience to analyze the impact of net consideration in patent settlements. Tr. at 25:6155-56 (Addanki). In the cited testimony, Professor Willig never discusses whether economists can draft guidelines. He opined that this is a "fresh topic," but not that this freshness impedes the ability to draft guidelines. Tr. at 29:7231-32 (Willig). In the cited testimony, Professor Bresnahan did not concede that the courts and agencies had no empirical experience applying the third prong of the test criteria that he used. To the contrary, he testified that "in the context of agreements between competitors, I think that's wrong." Tr. at 5:1026-27 (Bresnahan).

The finding is irrelevant because the proceeding is not a rule-making proceeding. Therefore, the question of writing guidelines is irrelevant.

3.223. Professor Bresnahan believes, however, that it is "important to test economic theories to see if they work in practice," (6 Tr. 1143 (Bresnahan)), and does not believe his test is ready for adoption by the Commission as antitrust policy. (5 Tr. 1023-25 (Bresnahan). Some of Professor Bresnahan's theories have proven incorrect in practice or have been rejected by the courts as lacking factual support. (6 Tr. 1146-49 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.223:

The proposed finding is not supported by the evidence. In the cited testimony, Professor Bresnahan testified that he would not advise the adoption of an "abbreviated rule which condemned any settlement with a...reverse payment." Tr. at 5:1025 (Bresnahan). This abbreviated rule does not correspond to the test criteria that Professor Bresnahan used in his economic analysis of the settlements at issue in this case. (*See* CPF 1129). In the cited testimony, Professor Bresnahan did not agree that theories he had developed had proven wrong in practice or had been rejected by the courts as lacking factual support. Tr. at 6:1147-49 (Bresnahan).

3.224. Other economists disagree with this part of Professor Bresnahan's test. (6 Tr. 1131-32 (Bresnahan)). These economists include Professor Willig, the former chief economist at the Antitrust Division. (*Id.* at 1132). They also include Carl Shapiro, another former chief economist at the Antitrust Division, (*id.*), and Richard Gilbert, yet another Antitrust Division Chief economist who worked extensively on the Antitrust Division's intellectual property guidelines. (*Id.* at 1135-39).

Complaint Counsel's Response to Finding No. 3.224:

The proposed finding is not supported by the evidence. In the cited testimony, Professor Bresnahan never conceded that Richard Gilbert disagreed with any particular part of the test criteria that he used in this case, nor with any particular statement from his expert report. Tr. at 6:1138-39 (Bresnahan).

[redacted]

3.225. Professor Gilbert wrote that "[b]ased on the allegations in the public record materials, these arguments appear to be anticompetitive arrangements to eliminate competition and to divide the monopoly profits of the successful branded drugs." (6 Tr. 1137-38 (Bresnahan) (SPX 836). Professor Gilbert further wrote that "[t]he fact that a settlement involves a payment from the patentee to the challenger is not sufficient to determine that the settlement is anticompetitive." (*Id.* at 1139) Professor Gilbert has not been retained by any of the parties in this matter. (*Id.* at 1136).

Complaint Counsel's Response to Finding No. 3.225:

The proposed finding is irrelevant to Professor Bresnahan's analysis. Professor Gilbert is discussing the implications of drawing a conclusions solely from the fact that there is a payment. Professor Bresnahan analysis was based on the economic incentives of the parties, the evidence that they acted on them, and the lack of actual, alternative justifications. CPRF 3.221, 3.226.

B. Bresnahan's Inference of Delay from the Fact of a Payment

3.226. Professor Bresnahan constructs a theoretical model to *infer* that a net payment delays entry relative to the outcome of the litigation. (4 Tr. 641 (Bresnahan); 24 Tr. 5760 (Addanki)). Specifically, Professor Bresnahan infers that Schering would only make a net payment if it would suffer "less competition under this settlement than its expectation of the amount of competition if the litigation were to go forward." (4 Tr. 613 (Bresnahan)). He opines that if an entrant would only find it worthwhile to settle if paid something, then we can be certain that the settlement contract deliver less competition than would litigating." (6 Tr. 1130 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.226:

The proposed finding is not supported by the evidence cited. The cited testimony at Tr. at 4:641 (Bresnahan) addresses Professor Bresnahan's qualifications, not the topic of what inferences can be drawn from a net payment. The proposed finding is contradicted by other evidence. In the cited testimony at Tr. at 24:5760 (Addanki), Dr. Addanki opines that Professor Bresnahan inferred delay from the "fact of a reverse payment." But Professor Bresnahan's conclusion that the payment for delay was based on (1) analysis of the parties' incentives, (2) evidence that the parties acted on their incentives, and (3) evidence that the $60 million payment was not for Niacor-SR or the other licensed products. CPF 1185 - 1208.

The finding is incomplete and misleading because Professor Bresnahan relies on more than just the existence of net consideration. Professor Bresnahan concludes that settlement delayed entry relative to what would have occurred because the net consideration was given in exchange for any entry date. Schering would only make a payment in exchange for Upsher

accepting a date if, the profits Schering makes under the settlement with the payment are more than Schering could have made under an alternative settlement that could have been reached and more than Schering expected to make by continuing the litigation. Similarly, Upsher is willing to accept a later entry date than it would accept in the absence of a payment and that it expects under litigation if it receives a payment. Therefore, the Schering-Upsher settlement delayed entry. The same analysis applies to the Schering-AHP settlement. CPF 1218-22.

1. Measurement of Delay

3.227. There is no proof of any alternate settlement with an earlier entry date. (26 Tr. 6325 (Kerr)). Professor Bresnahan does not know whether there were another settlement that the parties could have agreed to. (5 Tr. 1008-09 (Bresnahan)). Professor Bresnahan "can't tell us who would have won the litigation." (34 Tr. 8230 (Bresnahan)). Cases do not always settle. (12 Tr. 2676 (Mnookin)). There is no evidence that Schering or Upsher considered any entry dates earlier than September 1, 2001. (26 Tr. 6325 (Kerr)). In response to a question by complaint counsel, ESI's Mr. Dey stated that "if Schering had been willing to allow [ESI] onto the market before 2004," ESI "may have" been willing to settle for less money." (4 Tr. 632 (Bresnahan) (quoting Dey I.H.). Schering was unwilling to settle the ESI case with any entry date earlier than January 1, 2004. (CX 1482 at 99:17-100:6 (Alaburda I.H.)); (SPX 1222 at 101:9-17 (Alaburda I.H.)).

Complaint Counsel's Response to Finding No. 3.227:

The proposed finding is in part irrelevant. It is irrelevant whether Professor Bresnahan knows the details of an alternative settlement that the parties could have agreed to, or can tell us who would have won the litigation, or that cases do not always

settle. Professor Bresnahan, using standard economic principles, concluded anti-competitive harm. CPF 1217-22. The proposed finding is contradicted by more reliable evidence. In particular, there is evidence that Upsher considered settlements with entry dates earlier than September 1, 2001. CPF 183-184.

3.228. Thus, it is necessary to compare the settlement to the likely outcome if the parties had continued to litigate. (9 Tr. 1785 (Willig)). Professor Bresnahan also testified that a settlement agreement is pro-competitive if the percentage probability that the brand name would have won the patent case is larger than the percentage of the remaining patent life during which the generic agreed under the settlement to stay off the market. (6 Tr. 1211-12 (Bresnahan).

Complaint Counsel's Response to Finding No. 3.228:

The proposed finding is not supported by the evidence cited. The cited testimony at Tr. at 9:1785 (Levy) is not by Professor Willig, but rather by Dr. Nelson Levy. The testimony concerns the need to examine the effects of Niacor-SR on the liver in response to elevated liver enzyme levels, not the need to compare the settlement to the likely outcome if the parties had continued to litigate.

The proposed finding is incomplete. Professor Bresnahan's cited testimony is based on an assumption that the percentage probability is appropriately adjusted to reflect the time value of money, any anticipated expansion or deterioration in the market for the brand name's drug over time, and any delay in entry for the generic that would have occurred even if it won the patent case. Tr. at 6:1211-12.

The proposed finding is misleading to the extent that it suggests that one must assess the merits of the underlying patent litigation. Professor Bresnahan did not testify that it is

necessary to compare the settlement to the likely outcome if the parties had continued to litigate. Tr. at 6:1211-12 (Bresnahan); CPRF 3.315.

3.229. One of the fundamental flaws of the Bresnahan model is that he assumes that the patent holder would be unwilling to settle any earlier than the mean probable date of entry under litigation. (29 Tr. 7159 (Willig)). By the term "mean probable entry date," Professor Willig is referring to the weighted average between the early entry date that may occur if the generic prevails and the entry date at the end of the patent life that would occur if the incumbent patent holder wins, based on the probabilities that each entry date may occur. (29 Tr. 7160 (Willig)).

Complaint Counsel's Response to Finding No. 3.229:

The proposed finding is contradicted by other evidence. Professor Bresnahan relied on standard economic theory that says an incumbent with monopoly power and an entrant have incentives to delay uncertain entry. CPF 1161-65. These incentives exist whether or not the patent holder prefers a settlement with an entry date earlier than the mean probable entry date over litigation. CPF 1242. Moreover, Professor Bresnahan's conclusion that the settlements delayed entry was based on (1) analysis of the parties' incentives, (2) evidence that the parties acted on their incentives, and (3) evidence that the $60 million payment was not for Niacor-SR or the other licensed products. CPF 1185 - 1208.

2. Circumstances in Which Net Payment May Result in Earlier Genetic Entry

3.230. There are many circumstances in which settlement agreements that involve net payments to the generic could result in entry dates by the generic that are earlier than the likely outcome of litigation. (24 Tr. 5681 (Addanki); 25 Tr. 6166 (Addanki); 29 Tr. 7225-34 (Willig)).

Complaint Counsel's Response to Finding No. 3.230:

The proposed finding is incomplete and misleading. While some of the respondents' experts put forth theories that identify, under certain conditions, settlement with net consideration to the entrant that result in an earlier entry date than the likely outcome of litigation, there is no evidence why the parties would enter those settlements (CPF 1243-50), and a number of respondents' witnesses admitted that they were not aware of any such settlements in the real world, and none of respondents' witnesses offered real world examples of such payments. CPF 1415, 1417-1418.

a. Where a net payment is necessary to achieve settlement

3.231. Net consideration can be essential for the parties to settle their underlying dispute at all. (29 Tr. 7158, 7235 (Willig)). Such settlements can be socially desirable for both the parties and consumers. (29 Tr. 7158 (Willig)). A prohibition on such settlements would also result in businesses bearing undue risks and the costs of such risks, when such risks and costs could be avoided through a pro-consumer settlement of the underlying patent dispute. (29 Tr. 7235 (Willig)). Professor Bresnahan's approach would prohibit the use of net consideration to

obtain settlements that economists know are beneficial for consumers. (29 Tr. 7320 (Willig)).

Complaint Counsel's Response to Finding No. 3.231:

The proposed finding is incomplete. Professor Willig only identified theoretical situations in which an entrant and incumbent can settle only if the incumbent pays the entrant. There is no evidence that paying net consideration to the entrant has ever been essential to settle a patent litigation. CPF 1413-1425.

The proposed finding is further incomplete in that it says settlements with net consideration can be socially desirable, but Professor Willig never explained why parties would enter the theoretical settlements that he defined as socially beneficial. CPF 1245. Professor Willig testified that, in circumstances where net consideration is essential for parties to settle their underlying dispute, his models do not tell whether the resulting settlements will be beneficial or harmful to consumers. CPF 1246-1247. In fact, his models all predict anti-competitive settlements. CPF 1248. There is no evidence that such social beneficial settlements have ever occurred in the real world. CPF 1413-27.

b. Where the patent holder is risk-averse

3.232. A great deal of important economic phenomena are explained by risk aversion. Risk aversion is not just a theoretical nicety but is an essential part of our ability to understand real business behavior, as well as policy in circumstances where risk is important. (29 Tr. Willig)).

Complaint Counsel's Response to Finding No. 3.232:

The proposed finding is incomplete. The particular testimony supporting the finding is

not identified. The proposed finding is contradicted by other evidence. In economics, corporations are typically assumed to be risk-neutral, not risk averse. CPF 1266-1277.

3.233. A patent holder may be willing to settle for an entry date that is earlier than the mean probable entry date under litigation because of risk aversion or other litigation costs. A risk-averse incumbent is willing to give up some time relative to the mean probable date of entry under litigation in order to have a settlement. A risk averse patent holder can be expected to give up some of the expected value it associates with an entry date consistent with the likely outcome of litigation in order to eliminate the uncertainty of the litigation, and may be willing to settle for an entry date that is earlier than the likely entry date under litigation. (24 Tr. 5772-5774 (Addanki)). With risk-averse patent holders, one could expect to see settlements with entry dates earlier than the entry date under litigation. (24 Tr. 5775, 5780 (Addanki). A settlement conveys benefits to the patent holder by enabling it to avoid risk and other litigation costs. (29 Tr. 7165-66 (Willig)).

Complaint Counsel's Response to Finding No. 3.233:

Complaint counsel has no specific response.

3.234. Risk aversion thus affects the range of potential settlements in litigation. (29 Tr. 7071 (O'Shaughnessy)). The more risk averse a party is, the more avenues for exploration for settlement are opened. (29 Tr. 7071 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.234:

The proposed finding is incomplete. Risk aversion makes it easier for the parties

to settle without a payment of net consideration from the patent holder to the potential entrant. CPF 1264.

3.235. If the patent holder's "reservation date" is earlier than the mean probable date because of risk aversion or other litigation costs, net consideration could move the settlement to a later date than the patent holder's reservation date but to a date that will still be earlier than the mean probable date of entry under litigation. By the term "reservation date," Professor Willig means the earliest date at which the incumbent would be willing to allow the generic to enter the market rather than litigate. (29 Tr. 7161-62 (Willig)). This results in a settlement with an entry date that is favorable to consumers. (29 Tr. 7182 (Willig); (SPX 2332) (demonstrative).

Complaint Counsel's Response to Finding No. 3.235:

The proposed finding is incomplete. Professor Willig's theoretical models offer no explanation for why the parties would choose a settlement with an entry date that is favorable to consumers, which they prefer less, over an entry date that is unfavorable to consumers, which they prefer more. CPF 1245-1248.

3.236. Dr. Addanki gave an example of how risk aversion might affect the settlement of litigation. From an economist's perspective, a risk-averse firm will approach settlement negotiations by agreeing to accept less than the expected value of the litigation in order to obtain certainty. (24 Tr. 5767-68 (Addanki)). For example, a firm knows it has a 50 percent chance of prevailing in a litigation; if it prevails, it gets $20 million, while if it loses it gets nothing. (24 Tr. 5767 (Addanki)). The mathematical expected value of proceeding with litigation is the $20

million it would receive with a 50 percent probability, and a 50 percent probability of zero. (24 Tr. 5767 (Addanki)). On average, the firm will receive $10 million if it proceeds with the litigation. (24 Tr. 5768 (Addanki)). A risk neutral firm would settle the case for $10 million. (24 Tr. 5768 (Addanki)). A risk-averse firm, which includes most firms, would settle for less than $10 million, because of the uncertainty of obtaining the $10 million. (24 Tr. 5768 (Addanki).

Complaint Counsel's Response to Finding No. 3.236:

The proposed incomplete. A risk averse firm would be an exception and contrary to the general understanding in economics. CPF 1266-1277.

3.237. Thus, a risk averse firm might pay to obtain a settlement that is worse than it might receive under litigation, as long as the payment it makes leaves it better off than litigating, given its aversion to risk. (24 Tr. 5768 (Addanki)). By resolving the uncertainty, the firm can return to planning for the future without having the uncertainty hanging over its heads. (24 Tr. 5769 (Addanki)). It would be easier for them to come up with their investment strategies without the threat of litigation. (24 Tr. 5769 (Addanki)).

Complaint Counsel's Response to Finding No. 3.237:

The proposed finding is incomplete. It fails to acknowledge the general understanding in economics that firms are risk neutral, rather than risk averse. CPF 1266-1277.

3.238. Professor Bresnahan assumes that risk aversion would not affect the willingness

of the incumbent to settle. (29 Tr. 7192 (Willig)). The general presumption is that risk aversion is an important force among corporate decision-makers. (29 Tr. 7193 (Willig)).

Complaint Counsel's Response to Finding No. 3.238:

The proposed finding is contradicted by other evidence. Tr. at 4:609 (Bresnahan) (no evidence that Schering is risk averse); CPF 1266-1277 (the general understanding in economics that firms are risk neutral). The proposed finding is also contradicted by SPF 3.241 (that Bresnahan agrees that risk aversion can affect settlement negotiations). Moreover, risk aversion does not provide a reason why an incumbent would choose a pro-competitive settlement that it prefers less to anti-competitive settlement it prefers more. Tr. at 34:8115-16 (Bresnahan); *see also* CX 1759 (demonstrative illustrating testimony).

(1) Risk aversion defined

3.239. A "risk-averse" person is defined as someone who would be unwilling to take a fair bet. (29 Tr. 7069 (O'Shaughnessy); 6 Tr. 1150 (Bresnahan); 29 Tr. 7167 (Willig)). A risk-averse person would prefer a certain amount of money that is lower than the value of the fair bet. (Willig 7167). A person who strives for certainty is more risk-averse. (29 Tr. 7071 (O'Shaughnessy)). A person is risk-averse when the displeasure from losing a given amount of income is greater than the pleasure from gaining the same amount of income. (6 Tr. 1149-50 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.239:

Complaint counsel has no specific response.

3.240. A risk premium is the most one would be willing to pay to offload the risk. (29 Tr. 7169 (Willig)). This is not the same as an insurance premium, which is what an insurance company requires the insured to pay, but is the value of getting out from under the risk. (29 Tr. 7169 (Willig)). (*See also* SPX-2296: "[A] risk-averse individual would be willing to pay a premium above the expected value of loss in order to remove risk by purchasing an insurance policy.")

Complaint Counsel's Response to Finding No. 3.240:

SPX-2296 may not be cited as substantive evidence. SPX-2296 was admitted as a demonstrative only. JX 5. A demonstrative exhibit may only illustrate substantive evidence; a demonstrative is not substantive evidence. The quote from SPX 2296 is not in evidence nor has appropriate foundation been laid to show that the quote is within a recognized hearsay objection. No witness testified about the quote nor was the quote read into evidence.

3.241. Professor Bresnahan agrees that the parties' attitudes towards risk can affect the settlement negotiations. (6 Tr. 1152 (Bresnahan)). Professor Bresnahan agrees with Professor Willig that "a risk averse patent holder is willing to settle for an entry date that is earlier than the expected entry date under litigation in order to gain certainty." (24 Tr. 5769-70 (Addanki); 29 Tr. 7178 (Willig)).

Complaint Counsel's Response to Finding No. 3.241:

The proposed finding is irrelevant. Although Professor Bresnahan agrees that parties' attitudes towards risk can affect settlement negotiations, he found no evidence

that Schering is risk-averse. Tr. at 4:609 (Bresnahan) (no evidence that Schering is risk averse). Moreover, risk aversion does not provide a reason why an incumbent would choose a pro-competitive settlement that it prefers less to anti-competitive settlement it prefers more. Tr. at 34:8115-16 (Bresnahan); *see also* CX 1759 (demonstrative illustrating testimony).

3.242. If a firm undertakes risky projects, it does not mean that a firm is not risk-averse. (24 Tr. 5766 (Addanki)). A firm will bear risk in a project, but it must be compensated for bearing that risk. It will not pay the full expected value of the project, but will pay less than that, due to the premium it must obtain to be compensated for bearing the risk. (24 Tr. 5767 (Addanki))).

Complaint Counsel's Response to Finding No. 3.242:

The proposed finding is incomplete. It neglects the evidence of the general understanding in economics that firms are risk neutral, rather than risk averse. CPF 1266-1277.

(2) Risk aversion is widespread

3.243. Risk aversion is widespread. (24 Tr. 5764 (Addanki); 29 Tr. 7171 (Willig)). Nobel laureate economist Paul Samuelson explained: "People are generally risk-averse, preferring a sure thing to uncertain levels of consumption; people prefer outcomes with less uncertainty and the same average values. For this reason, activities that reduce the uncertainties of consumption lead to improvements in economic welfare." (24 Tr. 5764 (Addanki); SPX 2295) (demonstrative)).

Complaint Counsel's Response to Finding No. 3.243:

The proposed finding is irrelevant. We should not assume that corporations are risk averse because individual people are sometimes risk averse. Tr. at 34: 8066-8067 (Bresnahan). CPF 1272-1273.

3.244. Similarly, Nobel laureate economist Kenneth Arrow explained: "From the time of Bernoulli on, it has been common to argue that (a) individuals tend to display aversion to the taking of risks, and (b) that risk aversion in turn is an explanation for many observed phenomena in the economic world." (24 Tr. 5764 (Addanki); SPX 2295 (demonstrative); 29 Tr. 7178 (Willig)). Samuelson and Arrow are in the mainstream of economics on their thinking on risk aversion. (24 Tr. 5764 (Addanki)).

Complaint Counsel's Response to Finding No. 3.244:

The proposed finding is irrelevant. *See* CPRF 3.243. Furthermore, Kenneth Arrow changed the view on risk aversion expressed in the quotation in SPF 3.244 in response to the development of prospect theory. CPF 1294-1296 (based on excluded testimony).

3.245. Risk aversion also underlies the decision-making of most companies. (29 Tr. 7172 (Willig)). Thus, Professor Willig agrees with the observations of Frederick Scherer, a well-known industrial organization economist, who stated that "[o]nly the decision maker who attaches no significance whatsoever to avoiding risk will always choose alternatives with the highest best-guess payoffs. And such managers, empirical studies suggest, are rare." (29 Tr.

7172 (Willig)). (24 Tr. 5766 (Addanki); SPX 2296) (demonstrative)). Because corporations are simply collections of people, including risk-averse managers, the acts of a corporation will also be risk-averse. (24 Tr. 5766 (Addanki)).

Complaint Counsel's Response to Finding No. 3.245:

The proposed finding is contradicted by more reliable evidence. The quote on which Professor Willig and Dr. Addanki rely is not consistent with the current understanding of the risk preferences of corporations. CPF 1274. Nor can one conclude that the statement from Scherer represents his current opinion because the quote appeared in the 2nd edition of Professor Scherer's textbook but not the 3rd edition. CPF 1274. Furthermore, we should not assume that corporations are risk averse because individual people are sometimes risk averse. Tr. at 34:8066-8067 (Bresnahan). CPF 1272-1273.

3.246. From a corporation's point of view, risk aversion comes from individual people who manage the company and who are shareholders, as well as from a corporation's viewpoint that the more risk it bears, the higher is its cost of capital. (29 Tr. 7150 (Willig)). The investment community understands that risk requires more return for which to compensate, so a firm has a higher cost of capital when it is bearing more risk. (29 Tr. 7150 (Willig)).

Complaint Counsel's Response to Finding No. 3.246:

The proposed finding is contradicted by more reliable evidence. We should not assume that corporations are risk averse because individual people are sometimes risk averse. Tr. at 34:8066-8067 (Bresnahan). CPF 1272-1273. Furthermore, if there are risks that the corporation faces, "they may be ones that the corporation itself can

diversify, so that they're not very important to the corporation. Second, they are ones that the corporation's shareholders can diversify by also holding other corporations." Tr. at 34:8067 (Bresnahan). Furthermore, "diversifiable risk will not increase a firm's cost of capital." Tr. at 34:8077 (Bresnahan). The risks in the Schering-Upsher and Schering-ESI litigations were diversifiable. Tr. at 34:8078 (Bresnahan). Therefore, these risks could have no effect on Schering's cost of capital.

3.247. Risk aversion affects the investments managers are willing to make for their companies because a risk averse manager (or a manager for a risk averse company) tries to make investment decisions in a way that takes heed of the risks and tries to avoid unnecessary risks. (29 Tr. 7169 (Willig)). The manager will understand that one investment has a riskier posture than another, and for that reason, is less valuable, and so needs a higher expected return to compensate for the additional risk. (29 Tr. 7169 (Willig)).

Complaint Counsel's Response to Finding No. 3.247:

The proposed finding is irrelevant because corporations are not risk averse, CPRF 3.246, and corporations provide incentives to managers so that managers will act in a risk neutral fashion. CPF 1266, 1276.

3.248. Higher cost of capital is a cost of doing business that raises prices, deters or slows investment, and has negative business impacts both for the business itself and for the economy surrounding the business. (29 Tr. 7150 (Willig)). Thus, it is a "fair presumption" that companies are risk averse, as risk aversion explains the sensitivity to risk that underlies much of corporate

decision-making. (29 Tr. 7173 (Willig)).

Complaint Counsel's Response to Finding No. 3.248:

The proposed finding is irrelevant in part and contradicted by more reliable evidence in part. The effect of the higher cost of capital is irrelevant. CPRF 3.246. Professor Willig's testimony that it is a "fair presumption" that companies are risk averse neglects the evidence of the general understanding in economics that firms are risk neutral, rather than risk averse. CPF 1266-1277.

3.249. Professor Bresnahan agrees that people are generally risk averse, preferring a sure thing to uncertain levels of consumption. (6 Tr. 1157 (Bresnahan)). People prefer outcomes with less uncertainty in the same average values. (*Id.*) Professor Bresnahan believes that individuals, including business managers, are rarely risk-neutral. (6 Tr. 1158-59 (Bresnahan)). Professor Bresnahan also agrees that managers are generally risk averse, preferring a sure thing to uncertainty. (6 Tr. 1157-58 (Bresnahan)). Professor Bresnahan believes that only business managers who attach "no significance whatsoever to avoiding risk will always choose alternatives with the highest best-guess payoffs." (6 Tr. 1158-59 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.249:

The proposed finding is incomplete. While Professor Bresnahan testified that he agrees that people are generally risk averse, he also testified that "the argument goes off the rails" if we then conclude that corporations are risk averse. Tr. at 34:8066 (Bresnahan). Managers, whether risk averse or not, make risk neutral decisions when trying to maximize the profits of the firm. Tr. at 34:8072 (Bresnahan). And, corporations

provide incentives to managers to act in a risk neutral way. Tr. at 34:8067, 8082-83 (Bresnahan).

(3) Examples of risk aversion

(a) Risk aversion among litigants

3.250. James O'Shaughnessy, Schering's expert on the settlement negotiations of patent disputes, testified that he observed risk aversion "all the time" in his mediation and settlement practice, and that it is "palpable" in the negotiating room. (29 Tr. 7069 (O'Shaughnessy)). Risk aversion is particularly evident in business people, who are responsible for the profits and losses in their company. (29 Tr. 7069 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.250:

The proposed finding is incomplete. Mr. O'Shaughnessy did not testify that risk aversion was present in the settlement negotiations between Schering and Upsher, and between Schering and AHP. There is no evidence that Schering was risk averse in its decision to settle the Upsher or AHP litigations. CPF 1306-1311. Moreover, Mr. O'Shaughnessy's basis that negotiators are risk averse because they are responsible for the profit and loss for the product was not true for Schering. In both the Upsher and AHP negotiations, the major negotiators did not have future responsibility for K-Dur's profitability. CPF 1309-1310.

Furthermore, Mr. O'Shaughnessy was not offered as an expert in the risk preference of corporations or managers. Mr. O'Shaughnessy provided no explanation for how he determined that people are risk averse. He made mistakes in discussing risk aversion. Although Mr. O' Shaughnessy defined risk aversion correctly at Tr. at 29:7069,

he later misused the term. He said, "I mean by the end of the process, and you might take advantage and create some pessimism to drive a party to settlement. It's a function of risk aversion." Tr. at 29:7127 (O'Shaughnessy). Pessimism means a party has a lower chance of winning than they actually do and therefore pessimism has nothing to do with a party's risk preference. Tr. at 29:7226 (Willig). Saying that risk aversion allows one to increase a party's pessimism is inconsistent with Mr. O' Shaughnessy's testimony at Tr. at 29:7069, and it contradicts Schering's own proposed definition for risk aversion. Because of Mr. O' Shaughnessy's imprecision in using the term risk aversion, his opinions about risk aversion are unreliable and vague.

Further, the proposed finding is incomplete because Mr. O'Shaughnessy testified that higher sunk costs makes people more risk averse, but sunk costs should not affect decision-making. CPRF 3.253. Moreover, the economic literature contradicts Mr. O'Shaughnessy's testimony. CPF 1266-77. So does the literature on Prospect Theory. CPF 1278-99 (excluded evidence).

3.251. As Mr. O'Shaughnessy further explained, business managers place a value on certainty. (29 Tr. 7066 (O'Shaughnessy)). In his mediation practice, Mr. O'Shaughnessy has observed managers making compromises to achieve certainty. (29 Tr. 7066 (O'Shaughnessy)). He has heard executives say that they will pay for certainty to avoid unpredictability in the outcome of patent litigation. (29 Tr. 7066 (O'Shaughnessy)). Uncertainty affects investments, because investments can be made more rationally and reasonably under conditions of certainty. (29 Tr. 7067 (O'Shaughnessy)). Only with a greater degree of predictability can managers make

a plan to invest in the development of a new product, and to engage in the investments necessary to bring it to market. (29 Tr. 7067 (O'Shaughnessy)). When an extraordinary type of uncertainty appears, planning on these investments become risky to the ordinary businessman. (29 Tr. 7067 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.251:

The proposed finding is incomplete. In the cited testimony, Mr. O'Shaughnessy did not testify that the Schering business managers placed a value on certainty. There is no evidence that the Schering managers placed a value on certainty in the Schering-Upsher and Schering-AHP litigations. CPF 1309-1311; *see also* CPRF 3.250.

3.252. Risk aversion is a generally prevalent and important phenomenon for decision-making in the context of settling litigation. (29 Tr. 7839 (Willig)). Risk aversion is part of the environment in the context of negotiations to settle litigation. (29 Tr. 7295 (Willig)). It is widely understood that one of the principal purposes and benefits of settlement is to avoid the kind of risk that litigation entails. (29 Tr. 7339 (O'Shaughnessy)). Professor Willig bases this view on his long experience in the economic profession. (29 Tr. 7338-39 (Willig)).

Complaint Counsel's Response to Finding No. 3.252:

The proposed finding is incomplete. Neither Professor Willig nor Mr. O'Shaughnessy testified that risk aversion was present in the settlement negotiations between Schering and Upsher, and between Schering and AHP. There is no evidence that Schering was risk averse in its decision to settle the Upsher or AHP litigations. CPF 1306-1311. The fact that a benefit of settlement is certainty does not support the

proposition that either mangers or corporations are risk averse. The proposed finding is contrary to the general economic understanding the corporations are risk neutral. CPF 1266-77. By asserting that managers are risk averse, Professor Willig and Mr. O'Shaughnessy are asserting the managers are not maximizing the profits of their firm. Tr. at 34:8071-72 (Bresnahan)(to maximize the firm's profits the manager makes risk neutral decisions).

3.253. According to Mr. O'Shaughnessy, patent holders are risk-averse in intellectual property disputes. (29 Tr. 7070 (O'Shaughnessy)). Typically, a firm has sunk considerable costs into developing a product and the market for that product. (29 Tr. 7070 (O'Shaughnessy)). When a company makes such an expensive investment, it relies on the income stream from that investment, not only to recoup the investments and some premium for the risk, but also to fund continuing innovation. (29 Tr. 7070 (O'Shaughnessy)). With so much reliance placed on that stream of income, managers who are responsible for the asset are understandably risk-averse. (29 Tr. 7070 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.253:

The proposed finding is contradicted by other evidence. The costs of developing a product are classified as sunk costs, and they do not affect decisions taken later in time. Tr. at 6:1183, 1185 (Bresnahan) (sunk development costs do not affect later pricing decisions). Moreover, it ignores the fact that corporations can diversify against risk. CPF 1266.

3.254. Among the parties involved in intellectual property disputes, usually the patent holder is the most risk-averse. (29 Tr. 7071 (O'Shaughnessy)). That is typically the party who has relied on the patent system to shelter its investments in product development and market development, and needs to recoup that investment. (29 Tr. 7071-72 (O'Shaughnessy)). Parties in that position require certainty, thereby creating a higher degree of risk aversion. (29 Tr. 7072 (O'Shaughnessy)). The uncertainty associated with patent infringement litigation is unappealing to business managers, who want to "take that kind of uncertainty out of the plan so that they can get back to running the businesses." (29 Tr. 7073-74 (O'Shaughnessy)). Mr. O'Shaughnessy says that this type of risk aversion is "endemic in the field of patent infringement litigation." (29 Tr. 7074 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.254:

The proposed finding is incomplete. CPRF 3.250 (no evidence that Schering was risk averse in the Schering-Upsher and Schering-AHP litigations). The proposed finding is contradicted by other evidence. CPRF 3.253 (product development costs are sunk costs).

The finding is unreliable because Mr. O'Shaughnessy provided no bases for how he determined that patent-holders are more risk averse than alleged infringers. His testimony is inconsistent with Prospect Theory. CPF 1278-1299 (excluded evidence).

3.255. Mr. O'Shaughnessy's experience is consistent with economic theory, which dictates that a patent holder may be more risk-averse than an alleged infringer in a patent suit. (24 Tr. 5776 (Addanki)). The patent holder faces uncertainty in a litigation in that if they win,

they continue as before, and if they lose, they lose a revenue stream. (24 Tr. 5776 (Addanki)). The infringer faces similar uncertainties, with the good outcome being that they gain market entry, and the bad outcome being that they end up back where they started. (24 Tr. 5776 (Addanki)). The patent holder faces the prospect of loss, while the infringer faces the prospect of gain. (24 Tr. 5776 (Addanki)). This could affect the split in the remaining patent life agreed to in a settlement, because the risk aversion of the patent holder could induce the patent holder to accept a settlement with a very early entry date. (24 Tr. 5778 (Addanki)).

Complaint Counsel's Response to Finding No. 3.255:

The proposed finding is unreliable. Dr. Addanki provided no basis for this opinion. He cited no economic theory nor empirical studies that people facing losses are risk averse. His only basis was "common sense economic infusion." Tr. at 24:5776 (Addanki).

The proposed finding is contradicted by other evidence. Dr. Addanki's opinion about risk preferences at Tr. at 24:5776-5777 is contradicted Prospect Theory, which predicts that a patent holder in a negative (or loss) frame will be risk-seeking in a patent suit. CPF 1278-1299 (based on excluded testimony). Prospect Theory has been validated in more than one hundred empirical studies. CPF 1288 (based on excluded testimony).

3.256. Economic theory thus reveals how risk aversion on the part of the patent holder tends to move the reservation date to the early side of the mean probable date of entry under litigation. (29 Tr. 7174-75 (Willig)). For the patent holder, the risk premium, or the value of

offloading risk, becomes more powerful as the amount of money or value at stake increases. (29 Tr. 7175 (Willig)). In patent disputes, the incumbent has the greatest amount of profit or value at stake, because the incumbent stands to lose the profit flow that would come from one or two other competitors in the market, which is a smaller amount of money than that which the incumbent stands to lose. (29 Tr. 7175 (Willig)).

Complaint Counsel's Response to Finding No. 3.256:

The proposed finding is incomplete and misleading. In the cited testimony, Professor Willig fails to acknowledge the effect of diversification on risk preferences, and "when there's diversification, that means that risk matters far less." Tr. at 34:8076 (Bresnahan). Schering's risk in the K-Dur litigations was diversifiable. CPF 1308; CPRF 3.241; CPRF 3.255 (patent holder facing a loss will be risk-seeking, not risk averse) (based on excluded testimony).

3.257. Such risk aversion appeared to be at work in the judicial arm-twisting (29 Tr. 7079 (O'Shaughnessy)) that was creating risk for Schering in the ESI litigation. (*See* 12 Tr. 2714 (Driscoll)).

Complaint Counsel's Response to Finding No. 3.257:

The proposed finding is not supported by the evidence that is cited. Mr. O'Shaughnessy testified at Tr. at 29:7079 (O'Shaughnessy) that, as a mediator, he is envious of "a judge who can twist some arms," not that such arm-twisting creates risk aversion. Mr. Driscoll testified at Tr. at 12:2714 (Driscoll) that he thought that there was a risk of an unfavorable outcome in the ESI litigation, but that does not establish risk

aversion, as defined in SPF 3.239; *see also* CPF 1310.

(b) Insurance

3.258. "Whenever risk-averse individuals face uncertainty, they have a demand for insurance." (24 Tr. 5762 (Addanki); SPX 2290 (demonstrative)). "In response to increasing risk aversion, the firm always takes a higher insurance cover.... To safeguard against revenue risks, firms purchase among a wide range of insurance schemes ...." (24 Tr. 5762 (Addanki); SPX 2290) (demonstrative), quoting from Wong, Kit Pong "Insurance and the Behavior of Competitive Firms Under Revenue Risks: a Note").

Complaint Counsel's Response to Finding No. 3.258:

The proposed finding is not in evidence. The quoted statement is not from Dr. Addanki's testimony. SPX-2290 may not be cited as substantive evidence because it is was admitted as a demonstrative only. JX 5. A demonstrative exhibit is not substantive evidence. The quote from SPX 2290 is not in evidence nor has appropriate foundation been laid to show that the quote is within a recognized hearsay objection. No witness testified about the quote nor was the quote read into evidence. Dr. Addanki never discussed this quote during his testimony, and the demonstrative exhibit SPX 2290 was never used during his testimony.

3.259. Most people, when confronted with a situation facing uncertain outcomes, will be willing to pay something to have the uncertainty resolved (24 Tr. 5761-62 (Addanki)). Homeowners' insurance is an example of risk aversion, where people pay a premium to ensure

they will not lose large sums of money in the event of something bad happening to their house, even though the likelihood of the occurrence is very small. (24 Tr. 5762 (Addanki)).

Complaint Counsel's Response to Finding No. 3.259:

The proposed finding is irrelevant. An individual's decision to insure his or her private home has no bearing on the behavior of a corporation in the settlement of patent litigation. The proposed finding is contradicted by other evidence. The fact that people buy insurance does not necessarily mean that they are risk-averse. CPF 1297 (based on excluded testimony).

3.260. Insurance policies are purchased to offload the risk of an underlying loss and move that risk to an insurance company. (29 Tr. 7168 (Willig)). If you have insurance against your car blowing up, the risk of that happening is not on your shoulders because it has been removed by the insurance company. (29 Tr. 7168-69 (Willig)).

Complaint Counsel's Response to Finding No. 3.260:

The proposed finding is irrelevant and contradicted by other evidence. CPRF 3.259.

3.261. The purchase of insurance is one of the most widespread examples of risk aversion. As Nobel-laureate Kenneth Arrow explained, "The risk aversion hypothesis owes its durability, ... to its success in giving a qualitative explanation of otherwise puzzling examples of economic behavior. The most obvious is insurance, which hardly needs elaboration." Professor Bresnahan agrees. (34 Tr. 8232 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.261:

The proposed finding is incomplete and misleading. Professor Bresnahan agreed with Professor Arrow that "risk aversion giv[es] a qualitative explanation of otherwise puzzling examples of economic behavior," Tr. at 34:8238, but Professor Bresnahan also testified that the purchase of insurance by a firm "doesn't necessarily show that the corporation acts in a risk averse way." Tr. at 34:8081-8082 (Bresnahan) (explaining that corporations purchase insurance to insure that managers act in a risk neutral way). Furthermore, Nobel-laureate Kenneth Arrow later wrote that "the United States Government has offered flood insurance at rates which are well below their actuarial value...Under the usual hypothesis of risk aversion, any individual should certainly be willing to take a favorable bet...Yet until the Government increased the pressure by various incentives, very few took out this insurance." Tr. at 36:8535-8536 (Bazerman), CX 1770 (demonstrative) (based on excluded testimony). Professor Bazerman explained that the behavior identified by Professor Arrow is consistent with risk seeking, not risk aversion. Tr. at 36:8536 (Bazerman) (based on excluded testimony).

3.262. There is insurance on litigation offered in the field of intellectual property and patent disputes. However, this insurance is not commercially reasonable. (29 Tr. 7070-71 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.262:

The proposed finding is irrelevant.

3.263. After conducting an evaluation of Schering's insurance practices, Dr. Addanki concluded that Schering is risk-averse. (25 Tr. 6094-95 (Addanki)). Dr. Addanki reviewed documents and spoke with individuals who make investment decisions for Schering, including (25 Tr. 6095-96 (Addanki)) talking with the treasurer's office about Schering's insurance. (25 Tr. 6167 (Addanki)). Schering had insurance with lower deductibles than was customary in the industry, which told Dr. Addanki that Schering was risk-averse. (25 Tr. 6167 (Addanki)).

Complaint Counsel's Response to Finding No. 3.263:

The proposed finding is contradicted by other evidence. Observing the purchase of insurance does not establish that a corporation is risk averse. CPF 1275-1276. Dr. Addanki's analysis of Schering's risk preferences is flawed. CPF 1312-1315. There is no evidence that Schering was risk averse in settling its patent litigation with Upsher or ESI. CPF 1306-1317.

3.264. Dr. Addanki's analysis is confirmed by Schering's insurance practices: SPX 596, the Schering-Plough Corporate Insurance Schedule as of 8/1/01, shows Schering with insurance covering Domestic Property ($7.9 billion), Fidelity/Employee Dishonesty ($40 million), Cargo ($15 million), a long list of casualty insurance ranging up to $200 million, Foreign Property ($5.25 billion), Foreign Liability ($240 million), and other insurance (SPX 596). The total amount of coverage is $26.2 billion. On $7.9 billion in domestic property insurance coverage, the deductible is only $.5 million. On $5.25 billion in Foreign Property Insurance, there is no deductible.

Complaint Counsel's Response to Finding No. 3.264:

The proposed finding is contradicted by other evidence. CPRF 3.263. The evidence in SPX 596 does not provide sufficient information to determine whether the insurance is actuarially unfair because it does not estimate Schering's expected loss. Tr. at 34:8082 (Bresnahan). Moreover, the cited document was created in 2001 and sheds no light on Schering's practices at the time of the settlements. *See* SPX 596.

(c) Hedging

3.265. Hedging input costs to avoid uncertainty in future prices is another example of risk aversion. (24 Tr. 5763-64 (Addanki)). A firm that uses a lot of grain, silver, gold or some other material and regards the future prices that it must pay for those inputs as subject to uncertainty; it may pay to have that uncertainty resolved by hedging. (24 Tr. 5763 (Addanki)). There are different ways to hedge. (24 Tr. 5763-64 (Addanki)). A firm can hedge by just simply buying all the requirements for a year up front and putting them in storage. (24 Tr. 5763 (Addanki)). That way you pay the storage charges on them, but alleviate the uncertainty. (24 Tr. 5763 (Addanki)). Or a firm can hedge in the futures market, which also involves certain costs but relieves the uncertainty. (24 Tr. 5763-64 (Addanki)). There are different ways you can do it, but what the firm is trying to do is get rid of that uncertainty so it can plan with a less uncertain future. (Addanki 5763-64).

Complaint Counsel's Response to Finding No. 3.265:

Complaint counsel has no specific response.

3.266. Schering uses the first way of hedging to get rid of uncertainty regarding foreign currency fluctuations. (SPX 581 "Using Foreign Operations as a Hedge Against Foreign

Exchange Rate Exposure") (*See also* implementation of hedging strategy: SPX 593, SPX 594, SPX 595).

Complaint Counsel's Response to Finding No. 3.266:

The proposed finding is not supported by the evidence. SPX 581 outlines a possible hedging strategy, but it does not establish that Schering ever adopted the strategy, at any time. SPX 593 outlines requirements for Schering investments in commercial paper in 2001, and it does not establish that the strategy outlined in SPX 581 was ever adopted. SPX 594 is a list of approved banks for Eurodollar time deposits in 2001, and it does not establish that the strategy outlined in SPX 581 was ever adopted. SPX 595 is a list of approved providers for money market funds in 2001, and it does not establish that the strategy outlined in SPX 581 was ever adopted. There is no evidence that the strategy outlined in SPX 581 was ever adopted.

(d) Schering's risk aversion

3.267. Schering's risk aversion stems from the risk of losing its revenue stream from branded K-Dur 20 and K-Dur 10. (24 Tr. 6097 (Addanki)). In the K-Dur 20 patent litigation, Schering ran the risk of losing some of that revenue to A-B generic entry, because of mandatory substitution laws. (24 Tr. 6097-98 (Addanki)). Managers are risk averse. (24 Tr. 6069-6099 (Addanki)). Therefore, even though the sales of K-Dur 20 constituted less than 3 percent of Schering's overall sales, the individuals making the decisions regarding the product had a lot at stake. (24 Tr. 6098 (Addanki)).

Complaint Counsel's Response to Finding No. 3.267:

The proposed finding is contradicted by other evidence. There is no evidence that Schering was risk averse in its decision to settle the Upsher or AHP litigations. CPF 1306-1311. It is implausible that the negotiators for Schering would have been risk averse because they did not have future responsibility for K-Dur. Tr. at 34:8077 (Bresnahan); CPF 1309.

c. Where the generic is strapped for cash

3.268. A generic might be unable to settle for an entry date that it expects under litigation if a generic is short of cash. (24 Tr. 5781 (Addanki)). Professor Bresnahan has not modeled how long Upsher-Smith could have financially sustained its defense of the patent litigation. (4 Tr. 665 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.268:

The proposed finding is incomplete and irrelevant. There is no evidence that Upsher needed a payment to continue to operate its business. Tr. at 4:609 (Bresnahan). Therefore, this theoretical justification does not apply to the Schering-Upsher negotiation.

3.269. According to Dr. Addanki, cash shortage on the part of the generic is among the circumstances that may result in settlements with net consideration that permit entry earlier than the expected entry date under litigation. (24 Tr. 5790-91 (Addanki)). In the example where the litigation or settlement occurs in 2000, the patent expires in 2010, and there are equal odds of each party prevailing, the expected value of the litigation is an entry date of 2005. (24 Tr. 5790 (Addanki)). The risk averse patentee will settle for a date as early as 2004 in the example, and it

will give up the benefit of entry occurring as late as 2005 to eliminate the uncertainty of the litigation. (24 Tr. 5790 (Addanki)). However, the cash-strapped generic would worry that it cannot hold out until 2004, and would hope it could get an earlier cash infusion by winning the litigation. (24 Tr. 5791 (Addanki)). A settlement could result where the patent holder, recognizing the generic's need for cash, pays the generic some cash to ease its cash shortage and ends up with the settlement agreement in the range of 2004-2005. (24 Tr. 5791 (Addanki)). A settlement therefore might be structured so that the risk averse patent holder pays the cash-strapped entrant and ends up with an entry date, payment notwithstanding, that is before the likely outcome of the litigation. (24 Tr. 5792 (Addanki)).

Complaint Counsel's Response to Finding No. 3.269:

The proposed finding is incomplete and misleading. Dr. Addanki's testimony only identifies that, under those circumstances, there are settlements (1) that both parties prefer to litigation and (2) that provide an earlier entry date than the likely outcome of litigation. Dr. Addanki discusses an example where the risk averse patent holder pays the cash-strapped entrant and ends up with an entry date before the likely outcome of litigation, but under the conditions of his example there exist a multitude of settlements that the parties prefer to litigation and that provide less competition than litigation. Tr. at 34:8117-18 (Bresnahan) (cash-strapped entrant model); Tr. at 29:7190-91 (Willig) (cash-strapped entrant model). For any settlement that provides more competition than is expected under litigation, there are many anti-competitive settlements that the parties prefer. Tr. at 34:8117-18 (Bresnahan) (cash-strapped entrant model). Moreover, Dr. Addanki provides no analysis for why the parties would choose pro-competitive

settlements, which they prefer less, over anti-competitive settlements, which they prefer more. Tr. at 34:8117 (Bresnahan) (cash-strapped entrant model). His example predicts parties will choose anti-competitive settlements. Tr. at 34:8118 (Bresnahan) (cash strapped entrant model). Dr. Addanki only hypothesized that parties would not act on their incentives to enter an agreement that would be anti-competitive because of countervailing incentives to obey the law. CPF 1249. However this reliance on incentives to obey the law does not change the conclusion that Dr. Addanki's example predicts anti-competitive agreements because (a) he neither explained or identified the conditions under which those incentives would lead to pro-competitive results (b) the parties will not know at what point the entry date becomes anti-competitive (CPF 1256-1257) and (c) self-serving bias would likely undercut the incentives to obey the law (CPF 1258-1263). Furthermore, Dr. Addanki's example relies on the extreme assumption that publicly held, diversified corporations are risk-averse in patent litigation. CPF 1264-1277.

3.270. Professor Willig further developed the analysis for such a settlement between a cash-strapped generic and a risk-averse incumbent. While all economic actors prefer to receive income earlier rather than later, there are circumstances where a generic has a special need to have early cash flow early, to do business, for its investors or for some other reason. (29 Tr. 7187 (Willig)). Under this scenario, the reservation time for the generic is much earlier than it would have been if the generic did not need cash. (29 Tr. 7187 (Willig)). The generic would not be willing to wait until the mean probable date. (28 Tr. 7187-88 (Willig)).

3.271. Without net consideration under these circumstances, there would be no settlement. (29 Tr. 7188 (Willig)). The result would be litigation, which yields consumers only the mean probable date of entry under litigation. This is later than the entry date that would be enabled by some agreements, which do entail net consideration. (29 Tr. 7190 (Willig)).

Complaint Counsel's Response to Proposed Findings No. 3.270 and 3.271:

The proposed findings are incomplete and misleading. Professor Willig only identifies that, under those circumstances, there are settlements (1) that both parties prefer to litigation and (2) that provide an earlier entry date than the likely outcome of litigation. Under the conditions of Professor Willig's model there exist a multitude of settlements that parties prefer to litigation and that provide less competition than litigation. Tr. at 34:8117-18 (Bresnahan) (cash-strapped entrant model); Tr. at 29:7190-91 (Willig) (cash-strapped entrant model). For any settlement that provides more competition than is expected under litigation, there are many anticompetitive settlements that the parties prefer. Tr. at 34:8117-18 (Bresnahan) (cash-strapped entrant model). Nothing in Professor Willig's model explains why the parties would choose procompetitive settlements, which they prefer less, over anticompetitive settlements, which they prefer more. Tr. at 34:8117 (Bresnahan) (cash-strapped entrant model). In fact, his model predicts anti-competitive settlements. Tr. at 34:8118 (Bresnahan) (cash strapped entrant model).

3.272. At the time of its patent litigation with Schering, Upsher-Smith was a small pharmaceutical company. (23 Tr. 5401 (Troup)). Prior to settling the litigation with Schering,

Upsher Smith's month-to-month cash flows and net operating income varied from negative to positive and back. For example, from January through July 1996, Upsher Smith's "net cash from operating activities" and "corporate cash flow" were negative for four months and positive for three months. For those seven months, Upsher Smith's total cash flow was just $230,157. (USX 438 at USL 00473.) Through April 1997, Upsher's "net income from operating activities" was a negative $1,106,135. Total "corporate cash flow" for the first four months of 1997 was a negative $1,676,289. (USX 445 at USL 00888). For the first six months of 1997, Upsher's corporate cash flow was a negative $2,373,837. "Net cash from operating activities" for the first six months of 1997 was a negative $1,644,635. (USX 447 at USL 00948). Though August 1997, Upsher's "operating income" was a negative $1,077,660. (USX 449 at USL 01010). Upsher's "corporate cash flow" through August 1997 was a negative $3,537,824. (USX 449 at USL 01012.)

Complaint Counsel's Response to Proposed Finding No. 3.272:

See Complaint Counsel's Combined Response to Proposed Findings 3.272, 3.273, 3.274, 3.275, 3.276, 3.277 below.

3.273. In January 1997, Upsher's return on sales was a negative 11.1%, compared to its corporate target of 20%. Its return on assets was a negative 22.1%, compared to a corporate target of 25%. (USX 441 USL00775). By April 1997, Upsher's monthly return on assets was a negative 7.5%, with a negative 3.2% return on sales. For the year as a whole, return on assets was 6.7% and return on sales was 2.9%, well below Upsher's "minimum targets" of 25% and 20%, respectively. (USX 445 USL 00882). By June 1997, Upsher's operating return on assets

for the first half of 1997 was a negative 5.2% and its operating return on sales was a negative 6.3%. (USX 447 USL 00942). Part of Upsher's poor performance was due to higher than planned operating expenses in June 1997 of $226,000, of which $222,000 in that month were for patent-related legal expenses. (USX 447 at USL 00942).

Complaint Counsel's Response to Proposed Finding No. 3.273:

See Complaint Counsel's Combined Response to Proposed Findings 3.272, 3.273, 3.274, 3.275, 3.276, 3.277 below.

3.274. Between December 1996 and April 1997, Upsher Smith's stockholder equity declined from $7.4 million to $6.6 million. (USX 445 at USL 00887)

Complaint Counsel's Response to Proposed Finding No. 3.273:

See Complaint Counsel's Combined Response to Proposed Findings 3.272, 3.273, 3.274, 3.275, 3.276, 3.277 below.

3.275. Dr. Addanki, who analyzed Upsher's position as a basis for his opinion, testified that Upsher had dipped into its line of credit in the amount of $2 million, and that that amount had grown in the months leading up to the Schering settlement. (SPX 2076) (demonstrative); (24 Tr. 5782 (Addanki)). Dr. Addanki observed that Upsher's accounts payable, what it owed its creditors, increased in the months leading up to settlement . (SPX 2077) (demonstrative) (24 Tr. 5783 (Addanki)). He found that Upsher's cash position weakened and became negative in the months leading up the settlement, and Upsher was running out of cash. (SPX 2078) (demonstrative) (24 Tr. 5783 (Addanki)). Dr. Addanki found that Upsher's operating income

was also negative in the months leading up to settlement. (24 Tr. 5783 (Addanki) (SPX 2079) (demonstrative). He observed that Upsher's bills were piling up; it was borrowing money on its short-term line of credit. (24 Tr. 5788 (Addanki)). Upsher was short on resources to spend on marketing Klor Con, and Upsher employees had given up bonuses because they were short on resources and cash. (20 Tr. 4833-34 (Dritsas)) (24 Tr. 5789 (Addanki)).

Complaint Counsel's Response to Proposed Finding No. 3.275:

The proposed finding is based on exhibits (SPX 2076, SPX 2077, SPX 2078, and SPX 2079) that were not admitted as evidence of Upsher's financial condition. Tr. at 24:5788, 5781-87 (Addanki). They were admitted as a basis for Dr. Addanki's opinion, but Dr. Addanki never opined that Upsher had a cash flow problem. He only said that Upsher "may" have had a cash flow problem. Tr. at 25:6100 (Addanki). Furthermore, Dr. Addanki admitted that he did not do the proper evaluation necessary to determine that Upsher did indeed have a cash flow problem. CPF 1321. See also Complaint Counsel's Combined Response to Proposed Findings 3.272, 3.273, 3.274, 3.275, 3.276, 3.277 below.

3.276. Upsher's cash-strapped position was a factor in the Schering-Upsher settlement negotiations. Mr. Hoffman testified that Mr. Troup raised his need for cash in order to settle and Mr. Hoffman said that Schering would consider an extrinsic deal that stood on its own two feet. (15 Tr. 3543-44, 3559-60 (J.F. Hoffman)).

Complaint Counsel's Response to Proposed Finding No. 3.276:

This finding is misleading. Although Mr. Troup asked for cash in order to settle

the litigation, he asked for cash to replace his lost revenue, not to keep his business running. Moreover, he justified his demand based on the damage his product could do to Schering's revenue. CPF 167. Neither Mr. Troup nor anyone else from Upsher has claimed it needed a cash payment to maintain its business. CPF 1319. Troup's testimony is consistent, not with Upsher's being cash-strapped, but with Upsher asking for a share of Schering's monopoly profits. CPF 193, 1197-99.

See Complaint Counsel's Combined Response to Proposed Findings 3.272, 3.273, 3.274, 3.275, 3.276, 3.277 below.

3.277. The cost of the patent litigation was a drain on Upsher-Smith. (CX 232 USL 15395 ("Klor-Con® M litigation support continues to require substantial time and expenses." (January estimate $200K)). (CX 255 USL 02612 (January 14, 1997)) (23 Tr. 5406 (Troup)).. By May 7, 1997, Upsher's O'Neill wrote to Troup: "Klor-Con® M litigation support continues to require substantial time and expenses (Estimate for the remainder of 1997 $1,100 K)." ((CX 259 USL 15459.)) The testimony of Upsher's outside attorney, Mr. Canella, included a review of the monthly legal fees paid by Upsher in connection with the Klor Con®M litigation during the period of January 1996 through July 1997, which totaled roughly $2.8 million. (16 Tr. 3818-3823 (Canella); USX 83-USX 101). By May and June 1997, the monthly legal fees totaled $340,000 and $408,000, respectively. (16 Tr. 3823 (Canella)).

Complaint Counsel's Combined Response to Proposed Findings 3.272, 3.273, 3.274, 3.275, 3.276, 3.277:

The proposed findings are not supported by evidence and are incomplete. There is

no evidence that Upsher-Smith had a cash flow problem in 1997 when they entered into the settlement agreement. CPF 1318-1325. No witness or document from Upsher states that Upsher needed a payment to continue its business. CPF 1319. Upsher's own documents projected a net income of $7 million on $53 million in sales for 1997. CPF 1323. Upsher projected to bring in $1.7 million in the second half of 1997 from its new products, folic acid, St. John's Wort and Prevalite. Tr. at 25:6103-6104 (Addanki); CX 114 at USL 13152. [redacted] No expert has provided an opinion that Upsher had a cash-flow problem in 1997. Dr. Addanki said only that Upsher "may" have had a cash flow problem. CPF 1320. Furthermore, Dr. Addanki admitted that he did not do the evaluation necessary to determine if Upsher had a cash flow problem. CPF 1321. As a result of the settlement, Upsher received the first payment of $28 million in June 1997, but it paid out the entire amount to its stockholders, contradicting a conclusion that Upsher had a cash-flow problem. CPF 1322.

d. Where the parties have differing expectations concerning the outcome of litigation

3.278. Litigating parties have various expectations concerning the outcomes of litigation. (29 Tr. 7076-77 (O'Shaughnessy)). Parties are frequently optimistic about their chances of winning a litigation. (6 Tr. 1159 (Bresnahan)). Frequently, both parties are optimistic. (*Id.* at

1159-60). Professor Bresnahan classified the parties' competing expectations into three categories (optimistic, pessimistic and on target). (29 Tr. 7076-77 (O'Shaughnessy)). (29 Tr. 7197 (Willig)). Mr. O'Shaughnessy believes that there are two additional categories. (29 Tr. 7077 (O'Shaughnessy)). One of these categories is "wildly optimistic, well beyond the normal range of optimism." (29 Tr. 7077 (O'Shaughnessy)). Most of the parties that Mr. O'Shaughnessy has observed fall into either this wildly optimistic category or the highly optimistic group. (29 Tr. 7077 (O'Shaughnessy)).

Complaint Counsel's Response to Proposed Finding No. 3.278:

Complaint counsel has no specific response.

3.279. Too great a degree of optimism on the part of the parties is an impediment to settlement (29 Tr. 7079-80 (O'Shaughnessy)). Professor Bresnahan agrees that where each of two parties to a litigation believes they have a two-thirds chance of winning, a settlement is difficult to achieve. (6 Tr. 1160 (Bresnahan)).

Complaint Counsel's Response to Proposed Finding No. 3.279:

Complaint counsel has no specific response.

3.280. Over-optimism in negotiating is at tension with risk aversion. (29 Tr. 7077 (O'Shaughnessy)). Risk aversion drives parties towards settlement, because they are willing to pay for that certainty. (29 Tr. 7077 (O'Shaughnessy)). Optimism or over-optimism tends to drive them apart, creating a wider gap in their negotiating positions. (29 Tr. 7077-78 (O'Shaughnessy)).

Complaint Counsel's Response to Proposed Finding No. 3.280:

The proposed finding is incomplete. Risk aversion makes it easier for the parties to settle without a payment of net consideration from the patent holder to the potential entrant. CPF 1264.

3.281. Firms engaged in intellectual property litigation probably cannot reach a settlement if parties are more optimistic than risk averse. (29 Tr. 7078 (O'Shaughnessy)). If risk aversion is still the predominant factor underlying the negotiation, then settlement is possible. (29 Tr. 7078 (O'Shaughnessy)). The two would still be in tension, however, and it is not possible to determine what the likely outcome of the negotiation would be. (29 Tr. 7078 (O'Shaughnessy)).

Complaint Counsel's Response to Proposed Finding No. 3.281:

The proposed finding is incomplete because the degree of optimism varies over time. The degree of optimism and pessimism changes over the course of the litigation. Tr. at 29:7128 (O'Shaughnessy); *see also* SPF 3.289. As a mediator, Mr. O'Shaughnessy has sometimes created pessimism in litigating parties. Tr. at 29:7131-32 (O'Shaughnessy). Thus, optimism need not impede settlement.

3.282. Consistent with and extending upon Mr. O'Shaughnessy's analysis, Dr. Addanki explained from the economist's perspective how a generic's over-optimism might make settlement impossible in the absence of net consideration. (24 Tr. 5792-93 (Addanki)). With net consideration, a patent settlement could result that provides for earlier generic entry than is likely

to result from litigation. 24 Tr. 5778; 29 Tr. 7194-201; SPX 2331 (demonstrative); (SPX 2321); (SPX 2326); (SPX 2322); (SPX 2323); (SPX 2327); (SPX 2309).

Complaint Counsel's Response to Proposed Finding No. 3.282:

The proposed finding is incomplete and misleading. Dr. Addanki's justification is the same as Professor Willig's misplaced optimism model and therefore has the same flaws. CPF 1234. Like Professor Willig, Dr. Addanki has merely identified that, under the stated conditions, there are settlements with net consideration (1) that the parties prefer to litigation and (2) that provide for an earlier entry date than is expected under litigation. Dr. Addanki does not establish under what conditions those types of settlements will occur. Therefore, under Dr. Addanki's justification, for any settlement that provides more competition than is expected under litigation, there are many anti-competitive settlements that the parties prefer. CPF 1244. Dr. Addanki provides no analysis for why the parties would choose pro-competitive settlements, which they prefer less, over anti-competitive settlements, which they prefer more. Tr. at 34:8116 (Bresnahan) (misplaced optimism model. Furthermore, Dr. Addanki's example requires that the entrant believe that any feasible settlement is anti-competitive. CPF 1255. His example predicts parties will choose anti-competitive settlements. Tr. at 34:8116 (Bresnahan) (misplaced optimism model).

3.283. For example, assuming a risk-averse incumbent, the incumbent's reservation date for entry is earlier than the mean probable entry under litigation (29 Tr. 7194 (Willig)). If the generic is over-optimistic, it believes it has a better chance of winning the case than it actually

does, and holds out for an optimistically early entry date, which it believes is equivalent to its odds of prevailing in the litigation. (29 Tr. 7195 (Willig)). In this example, a settlement is not possible. (*Id.*).

Complaint Counsel's Response to Proposed Finding No. 3.283:

Complaint counsel has no specific response.

3.284. There may be a range of settlement dates that can be supported by an agreement with net consideration, however, that still leaves consumers better off than they would be under litigation. (29 Tr. 7196 (Willig)).

Complaint Counsel's Response to Proposed Finding No. 3.284:

The proposed finding is incomplete and misleading. CPRF 3.282.

3.285. In this situation, if net consideration were banned, there would be no settlement and consumers would face litigation with a mean probable entry date that is later than would be obtained through the settlement that included net consideration. (29 Tr. 7196 (Willig)).

Complaint Counsel's Response to Proposed Finding No. 3.285:

The proposed finding is incomplete and misleading. Professor Willig never establishes that, under litigation, consumers would face a mean probable entry date that is later than would be obtained with net consideration. To the contrary, Professor Willig's model predicts anti-competitive settlements, in which case entry would be earlier under litigation. CPF 1248. In the cited testimony, Professor Willig opined if net consideration were banned, the probable outcome of litigation might be later than settlements with net

consideration. He did not opine that the mean probable date would be later. Tr. at 29:7196 (Willig).

The finding is further misleading because Professor Willig has not established that parties have ever used net consideration in the real world to overcome this particular type of impasse. CPF 1418.

3.286. Professor Willig's varied-assessments-of-success analysis addresses the question of whether a payment to delay will necessarily delay entry (SPX 2312) (29 Tr. 7229 (Willig)). It shows that there are circumstances that net payment results in a pro-competitive settlement where neither party is risk averse and where parties have disparate views of the likelihood of success. (SPX 2312) (29 Tr. 7229 (Willig)).

Complaint Counsel's Response to Proposed Finding No. 3.286:

The proposed finding is incomplete. Under Professor Willig's varied-assessments model, both parties believe that they are entering an anti-competitive settlement when they reach a settlement with net consideration. CPF 1254. The proposed finding is contradicted by other evidence. CPF 1248 (the varied-assessment model predicts anti-competitive settlements). Professor Willig does not opine that his model predicts that parties will reach pro-competitive settlements. CPF 1247. At most, the parties reach a pro-competitive settlement only if they are both making a mistake. Tr. at 34:8112 (Bresnahan).

3.287. For example, where the incumbent has a pessimistic view of its chances of

success relative to the true odds, it will have a reservation date on the early side of the mean probable date of entry. (29 Tr. 7225-26 (Willig)). The incumbent is not assumed to be risk averse or to have other costs of litigation. (SPX 2333) (demonstrative); (29 Tr. 7226 (Willig)). Where the generic has an overly optimistic view of its odds of winning the case relative to the true probabilities, it will hold out for an earlier time entry than the mean entry date. (SPX 2333) (demonstrative); (29 Tr. 7226-27 (Willig)). There is a gap between the reservation dates because the entrant's optimism is stronger than the incumbent's pessimism. (SPX 2333) (demonstrative) (29 Tr. 7227 (Willig)).

Complaint Counsel's Response to Proposed Finding No. 3.287:

The finding is incomplete. CPRF 3.286.

3.288. The gap prevents the litigants from finding a mutually agreeable date of entry. (SPX 2333) (demonstrative); (29 Tr. 7226 (Willig)). Consumers would benefit from any settlement that leads to an entry date any time up to the mean probable date of entry. (SPX 2333) (demonstrative); (29 Tr. 7227 (Willig)). Here, net consideration would permit the parties to close the gap between their differing reservation dates, but on dates that would still be earlier than the mean date of entry. (SPX 2333) (demonstrative); (29 Tr. 7228 (Willig)).

Complaint Counsel's Response to Proposed Finding No. 3.288:

The proposed finding is incomplete. Professor Willig's model only identifies that, under certain conditions, there are settlements with a payment (1) that the parties prefer to litigation and (2) that provide more consumer surplus than is expected under litigation; the model does not predict that the parties will enter those settlements. Nothing in

Professor Willig's model of varied assessments explains why the settling parties would choose a settlement with entry earlier than the mean probable date of entry under litigation, which they prefer less, over a settlement with entry later than the mean probable date of entry, which they prefer more. CPF 1245. Professor Willig's model of varied assessments predicts anti-competitive settlements. CPF 1248.

3.289. Pessimism is not as common as optimism, but the distribution of parties between pessimistic, optimistic and equal assessment changes over the course of the litigation. (29 Tr. 7128 (O'Shaughnessy)). As a mediator, Mr. O'Shaughnessy has sometimes created pessimism in litigating parties. (29 Tr. 7131-32 (O'Shaughnessy)). (12 Tr. 2714 (Driscoll)).

Complaint Counsel's Response to Finding No. 3.289:

Complaint counsel has no specific response.

3.290. Again, in this scenario, a competitive outcome is not assured. (29 Tr. 7229 (Willig)). Professor Willig's model does not reveal whether the resulting settlement will be earlier than the mean probable entry date, and thus beneficial to consumers, or later than the mean probable entry date. (29 Tr. 7229 (Willig)). The model simply shows that net consideration may be necessary to achieve socially preferable kinds of settlements. (29 Tr. 7229 (Willig)).

Complaint Counsel's Response to Finding No. 3.290:

The proposed finding is incomplete. Not only is the competitive outcome not assured, nothing in Professor Willig's model of varied assessments explains why the

settling parties would choose a settlement with entry earlier than the mean probable date of entry under litigation, which they prefer less, over a settlement with entry later than the mean probable date of entry, which they prefer more. CPF 1245. Professor Willig's model of varied assessments predicts anti-competitive settlements. CPF 1248.

e. Where the generic is concerned about third party entry

3.291. Professor Willig analyzed the situation where a third party, not subject to the litigation, might enter the market during the time span of the patent life. (29 Tr. 7202, 7213 (Willig)) (SPX 2311); (SPX 2334) (demonstrative). An incumbent who expects further entry will accept settlements on the early side of the mean probable entry date under litigation (Willig 7203), because the increased competition after the third party has entered reduces the profit opportunities to the incumbent after such entry. (29 Tr. 7204 (Willig) (SPX 2334) . For the same reason, the generic will accept an entry date significantly earlier than the mean probable entry date. (29 Tr. 7205 (Willig)).

Complaint Counsel's Response to Finding No. 3.291:

Complaint counsel has no specific response.

3.292. However, because the stakes in the third party's entry differ as between the incumbent and the generic, their reservation dates do not move to the same extent and there is a gap between those dates. (29 Tr. 7205 (Willig)). The litigating parties can close the gap with net consideration, resulting in entry potentially earlier than the mean probable date of entry under litigation. (29 Tr. 7206 (Willig)).

Complaint Counsel's Response to Finding No. 3.292:

The proposed finding is incomplete and misleading. Professor Willig's model only identifies situations in which there are settlements that the parties prefer to litigation and that provide more competition than is expected under litigation. CPF 1242-44. Nothing in Professor Willig's model of third party entry explains why the settling parties would choose a settlement with entry earlier than the mean probable date of entry under litigation, which they prefer less, over a settlement with entry later than the mean probable date of entry, which they prefer more. CPF 1245. Professor Willig's model of third party entry predicts anti-competitive settlements. CPF 1248.

3.293. While a settlement with net consideration may accelerate entry compared to the mean probable entry date under litigation, consumers would find the settlement welfare-enhancing even if the break-even date from a consumer's perspective is later than the mean probable date of entry under litigation. (29 Tr. 7205 (Willig)).

Complaint Counsel's Response to Finding No. 3.293:

The proposed finding is not supported by the evidence. There is no evidence that a settlement with an entry date later than the mean probable date of entry under litigation would always or even frequently be welfare-enhancing. The evidence shows only that it is theoretically possible that under certain conditions, a settlement with an entry date later than the mean probable date of entry under litigation would be welfare-enhancing. There is no evidence that those conditions do exist in the real world.

In the cited testimony, Professor Willig said "it's quite possible that the break-even entry

date from the consumer perspective is moved to the right of the mean probable date of entry under litigation." 29:7205 (Willig) (the necessary condition under his model for a settlement with an entry date after the mean probable date of entry under litigation to be pro-competitive). He never said that settlements after the mean probable date of entry under litigation would always be welfare-enhancing. He admitted that whether a settlement after the mean entry date is welfare-enhancing depends on the algebra in his model. Under certain conditions, settlements after the mean probable date of entry under litigation would not be welfare-enhancing. Tr. at 29:7269 (Willig) (the consumer arrow does not go to the right of the mean probable date of entry under litigation).

Under Professor Willig's third party entry model (SPX 2311), settlements with entry dates before the mean probable date of entry under litigation could provide less consumer welfare than litigation. The inequality at line 13 defines the criteria for when a settlement with an entry date "t" provides more consumer welfare than is expected under litigation. Under that inequality, a settlement provides more consumer welfare than is expected under litigation if $t \leq ps + p(\theta - s)\,((2\beta + \delta)/(\alpha + \mu - 2\beta - \delta))$. In Professor Willig's notation, the mean probable date of entry under litigation is defined as $p\theta$. SPX 2322 at p. 33. If $p\theta > t > ps + p(\theta - s)\,((2\beta + \delta)/(\alpha + \mu - 2\beta - \delta))$, then a settlement with entry date "t" provides less competition than litigation even though the entry date "t" is earlier than the mean entry date under litigation. By performing simple algebra, $p\theta > ps + p(\theta - s)\,((2\beta + \delta)/(\alpha + \mu - 2\beta - \delta))$ when $(2\beta + \delta)/(\alpha + \mu - 2\beta - \delta) < 1$.

By contrast, the requested finding (that there exist settlements with entry dates after the mean entry date under litigation that provide more consumer welfare than is

expected under litigation) is true if and only if $(2\beta + \delta)/(\alpha + \mu - 2\beta - \delta) > 1$.

Professor Willig provided no testimony on how often the ratio $(2\beta + \delta)/(\alpha + \mu - 2\beta - \delta)$ is likely to be greater than or less than one. The terms refer to duopoly profits (β), deadweight loss under duopoly (δ), monopoly profits (α), and deadweight loss under monopoly (μ). CPF 1370. He provided no testimony on whether there is any real-world example where the ratio $(2\beta + \delta)/(\alpha + \mu - 2\beta - \delta) > 1$.

3.294. Consumers are willing to wait longer for entry, if they have to, because when all parties are in the market, the outcome is highly competitive and very advantageous to consumers. (29 Tr. 7205-06, 7209, 7232-33 (Willig)).

Complaint Counsel's Response to Finding No. 3.294:

The evidence does not support the finding. There exist settlements with entry dates later than the mean probable date of entry under litigation that provide more consumer surplus than is expected under litigation only under specific assumptions. CPRF 3.293. Moreover, it is an assumption of the model that three competitors is very advantageous to consumers: "I have assumed that when all three of those firms are there, the outcome is highly competitive, very advantageous to consumers and so consumers...." Tr. at 29:7205-06 (Willig). Therefore, the finding is misleading to the degree it implies that consumers value three or more competitors significantly more than two competitors or that Professor Willig provided an opinion on whether consumers value three competitors significantly more than two competitors.

3.295. If net consideration were banned under this scenario, there would be a systematic gap between the reservation dates of the generic and the incumbent, because of the entry by the third party. (29 Tr. 7206 (Willig)). No settlement would occur that entails only a split in the remaining patent life and consumers would be worse off.

Complaint Counsel's Response to Finding No. 3.295:

Complaint counsel has no specific response.

3.296. Upsher-Smith projected generic entry by firms other that Schering's generic division, Warrick. (CX 186 FTC 155814) ("Due to the brief exclusivity period, early penetration and acceptance of physicians will be important to gain and hold physician DAW prescriptions and maintain share after market entrance of multiple competitors six months following the launch." (CX 187 FTC 137992)). "Within six months of the Klor-Con M20 launch, there will be at least three generic competitors in the market driving price erosion." (USX 392 FTC 151426; USX 610 USL 13995). In fact, Upsher expressed concern that as many as four other generic producers would enter with other generic products, including ESI Lederle, Andrx, an unnamed "other" generic producer and Schering's generic Warrick division. (CX 190 FTC 138945, CX 190 FTC 138948.)

Complaint Counsel's Response to Finding No. 3.296:

This proposed finding is incomplete and misleading to the extent that it implies that the third-party entry model has any applicability to the Schering-Upsher settlement negotiations. Professor Willig did not provide an opinion that the model applied to the Schering-Upsher settlements. CPF 1332. No document nor any testimony stated that

Upsher's concern about a third-party entrant prevented Upsher and Schering from settling without a payment. CPF 1334. Nor did any document or any testimony state that the issue was ever discussed during the settlement discussions. The cited documents have no relevance to the applicability of the third-party entry model to the Upsher settlement because none were created prior to the settlement. CX 186 is dated August 8, 2000. CX 187 is dated March 22, 2001. The cited page of USX 392 has no date but the data used in the document included actual sales data from 2000. USX 392 at Upsher-Smith FTC 151434. The cited page of USX 610 does not have a date, and a later page is date December 22, 1999. USX 610 at Upsher-Smith FTC 14009. For page 138945 of CX 190, there is no date, but the page discusses AHP entry as September 1, 2004. Because that date was agreed to after the Upsher settlement, the page was created after the settlement. Page 138948 of CX 190 is dated September 1999.

3.297. Well after the settlement, Upsher noted its continuing concern about entry: "Klor Con® M10 does not have 180-day exclusivity. Additional discussions will take place regarding our ability to launch if another competitor (Andrx) receives approval of a 10mEq and launches it. Management is reviewing this topic so that this risk may be assessed. Marketing views this as high risk with high impact. If a competitor launched a generic to K-Dur® 10 and Upsher-Smith is not allowed to compete, the 20mEq market will collapse in units and price prior to our launch." (CX 190 FTC 138947)

Complaint Counsel's Response to Finding No. 3.297:

This proposed finding is incomplete and misleading to the extent that it implies

that the third-party entry model has any applicability to the Schering-Upsher settlement negotiations. *See* CPRF 3.296.

3.298. As early as March 1995, Schering was aware that Andrx pharmaceuticals was developing a 20 mEq potassium chloride formulation. (CX 13) (4 Tr. 717-18 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.298:

This proposed finding is incomplete and misleading to the extent that it implies that the third-party entry model has any applicability to the Schering-Upsher settlement negotiations. CPRF 3.296.

f. Where the parties have asymmetric information

3.299. When parties negotiate, they bring to the table their understanding of the dispute. (29 Tr. 7074 (O'Shaughnessy)). These parties know their own positions well and have a fairly good understanding of their adversary's position. (29 Tr. 7074 (O'Shaughnessy)). In some cases, the parties have some experience in negotiation. (29 Tr. 7074 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.299:

Complaint counsel has no specific response.

3.300. The parties also carry with them their normal fears and worries into the conference room. (29 Tr. 7074-75 (O'Shaughnessy)). One such fear is based on experiences of "buyer's remorse." (29 Tr. 7075-76 (O'Shaughnessy)). The parties worry that the other side will have information on a matter of consequence to the outcome that is superior to theirs, and that

when the transaction is completed, the other party will have bested them. (29 Tr. 7076 (O'Shaughnessy)). People who lack information on an issue of consequence usually "dig their heels in," negotiating very hard. (29 Tr. 7076 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.300:

Complaint counsel has no specific response.

3.301. Professor Mnookin added that parties often "have different information, and as a consequence, they may have different assessments" of what the litigation opportunities and risks are. (12 Tr. 2676 (Mnookin)).

Complaint Counsel's Response to Finding No. 3.301:

Complaint counsel has no specific response.

3.302. Professor Willig demonstrated that in cases where litigating parties have different information, net consideration could act as a signal resulting in a settlement that does not delay entry past the likely date of entry under litigation. (SPX 2324, SPX 2329; 29 Tr. 7223-24 (Willig)). Signaling is the phenomenon where one party has superior information to the other about an issue of mutual concern. (29 Tr. 7213 (Willig)). The other party understands that the first has superior information. (29 Tr. 7213 (Willig)). Signaling refers to the use of some means (articulation, money, rights, etc.) by the party with the superior information to the other party, demonstrating that it has superior information. (29 Tr. 7214 (Willig)). When two parties cannot come to a mutually beneficial arrangement because of asymmetric information, the party with superior information can use net consideration to convey the missing information to the other

party and make the deal work. (29 Tr. 7215 (Willig)).

Complaint Counsel's Response to Finding No. 3.302:

The finding is not supported by the cited evidence. Nothing on page 7215 states that net consideration can be used to convey the missing information. Professor Willig, on page 7215, states that "signaling is a device that the party with the better information can employ so as to convey the missing information and make the deal work." On page 7215, he does not identify net consideration as a signal.

3.303. Signaling may occur in a patent dispute where the incumbent has superior information about the value of rights in dispute in the patent litigation. (29 Tr. 7217 (Willig)). For example, the incumbent may have better information about new technologies that it is developing and which would be valuable for the incumbent but which would undermine the value of the rights to the product whose patent is in dispute. (29 Tr. 7217 (Willig)). Alternatively, the incumbent may have superior information about the progress that other possible generic entrants are making toward entering the market so as to shorten the useful economic life of the patent for the litigating entrant. (29 Tr. 7218 (Willig)). And even if the incumbent does not have asymmetric information, the litigating entrant may assume that the incumbent has it. (29 Tr. 7218 (Willig)).

Complaint Counsel's Response to Finding No. 3.303:

Complaint counsel has no specific response.

3.304. For example, if the entrant believes the incumbent has superior information regarding the economic life of the patent, the entrant may hold out for a relatively sooner entry date, because of its justified fear that the economic life of the patent is short. (29 Tr. 7218-20 (Willig)).

Complaint Counsel's Response to Finding No. 3.304:

Complaint counsel has no specific response.

3.305. If the incumbent knows that, in fact, the economic life of the patent is long, the incumbent will want a later entry date than the entrant does. (29 Tr. 7220 (Willig)). There will be no settlement. (29 Tr. 7220 (Willig)).

Complaint Counsels' Response to Finding No. 3.305:

Complaint counsel has no specific response.

3.306. Here, the offer of a settlement with sufficient net consideration takes on the role of the signal. (29 Tr. 7221 (Willig) (SPX 2335) (demonstrative). There are welfare-enhancing settlements that are made possible by the conveyance of net consideration. (29 Tr. 7221 (Willig)). By making the offer of an entry date with a measured amount of net consideration, the incumbent tells the skeptical litigating entrant that the incumbent recognizes that the life of the patent is long. (29 Tr. 7221 (Willig)). A settlement is made possible by the passage of net consideration, and would give consumers more competition than they would receive on average if the parties continued to litigate. (29 Tr. 7222 (Willig))

Complaint Counsel's Response to Finding No. 3.306:

This proposed finding is not supported by the evidence. Professor Willig's signaling model only identifies situations in which there are settlements that the parties prefer to litigation and that provide more competition than is expected under litigation. CPF 1242-44. Nothing in Professor Willig's signaling model explains why the settling parties would choose a settlement with entry earlier than the mean probable date of entry under litigation, which they prefer less, over a settlement with entry later than the mean probable date of entry, which they prefer more. CPF 1245. Professor Willig's signaling model predicts anti-competitive settlements. CPF 1248.

3.307. If net consideration were prohibited in this example, then the gap between the parties' positions would prohibit the settlement. (29 Tr. 7222 (Willig)). Again, the risk-bearing costs that would follow from litigation would fall on the incumbent, and consumers would be held to the mean probable date of entry under litigation, which is later than some of the deals that could have occurred if net consideration were allowed. (29 Tr. 7222 (Willig)). Here, the risk-averse incumbent is willing to move the date of settlement to the early side as its way to pay for the insurance to get out from under the endemic risk associated with litigation. (29 Tr. 7223 (Willig)).

Complaint Counsel's Response to Finding No. 3.307:

This finding is contrary to more reliable evidence. Although Professor Willig testified that banning net consideration would prevent a settlement under the signaling model, he never explained why net consideration is the only possible way to signal information. Professor Willig himself gave two examples in other contexts where

signaling did not require net consideration. Tr. at 29:7215-16 (Willig) (signaling by appearance in a job interview and signaling by providing information in selling a used car). Therefore, the evidence does not support a finding that banning net consideration would prevent settlements under the conditions of the settlement model because there is no evidence that net considerations is the only possible signal.

3.308. The foregoing is not a complete list of circumstances where net consideration can result in welfare enhancing settlements. Economists have not undertaken research aimed at identifying all of the underlying factors that would lead net consideration to be a valuable tool for obtaining socially beneficial settlements of patent disputes. (Willig 7232).

Complaint Counsel's Response to Finding No. 3.308:

This finding is irrelevant and misleading. It is standard economics that paying a potential competitor to delay entry harms consumer welfare. Dr. Bresnahan explained how net consideration harms competition and concluded that the conditions were satisfied in this case, CPF 1129-35, and both of Schering's experts concede that such agreements can harm competition. Tr. at 29:7283 (Willig), Tr. at 25:5950 (Addanki) (Addanki agreed that net consideration that has to do with delaying the entry date could harm competition). In commenting on the complaint in this case, Professor Gilbert wrote that "[b]ased on the allegation in the public record materials, these agreements appear to be anti-competitive arrangements to eliminate competition..." Tr. at 6:1137-38.[redacted]

[redacted] Every model proposed by the respondents' experts predicts anti-competitive settlements. CPF 1248. There is no evidence or opinion testimony that net consideration has been used to facilitate a pro-competitive settlement. CPF 1413-27. There has been considerable research which leads to the following conclusions. Theoretically, there is no reason to believe parties would ever enter a pro-competitive settlement were they allowed to use net consideration; empirically, there is no evidence that they ever have; theory predicts anti-competitive settlements if net consideration is given for delay; and the evidence supports the conclusion that the parties to the settlements at issue agreed to exchange net consideration for delay and harm competition. CPF 1227-1232. The finding is further irrelevant because hypothetical justifications not considered by the parties at the time of the negotiations cannot justify the payments for the entry date.

3.309. There are therefore "plenty of circumstances" where the opportunity to use net consideration creates the opportunity for a mutually advantageous settlement between the incumbent and the generic that consumers will find preferable to the mean probable entry date under litigation. (29 Tr. 7207 (Willig)). From an economist's viewpoint, there would be harm in presuming that net consideration was anticompetitive. (29 Tr. 7236 (Willig)).

Complaint Counsel's Response to Finding No. 3.309:

The finding is contrary to more reliable evidence and irrelevant. No one has identified the conditions under which the parties would actually enter a pro-competitive

settlement using net consideration. There is no evidence that net consideration has been used to facilitate pro-competitive settlements; therefore, Professor Willig has no basis to attack a rule that presumes net consideration is anti-competitive. presuming that net consideration was anti-competitive.

The finding is irrelevant because Professor Bresnahan did not presume net consideration was anti-competitive. CPRF 3.226.

The finding is further irrelevant because none of the theoretical models have any applications to the settlements at issue. CPF 1300.

3.310. That does not mean that net consideration could not undergird a settlement that is adverse to consumers. What it means is that you cannot use net consideration as a shortcut to determine whether net consideration results in an anticompetitive agreement. (29 Tr. 7233-34 (Willig)).

Complaint Counsel's Response to Finding No. 3.310:

The proposed finding is irrelevant to the degree it is criticizing the use of "net consideration as a shortcut." From an economic perspective, Professor Willig is criticizing a standard that was not used by Professor Bresnahan. CPRF 3.226. From a legal standard, Professor Willig is not competent to render an opinion on what evidence is necessary to conclude that an agreement is anti-competitive. Moreover, both the theories and the empirical evidence in this case support the conclusion that net consideration given in exchange for an entrant's agreement not to enter for a period of time will harm consumers. CPF 1227-1228; 1300; 1338-1340.

3.311. Inferring an agreement to delay from net consideration would be incorrect, and a dangerous approach. (29 Tr. 7233-34 (Willig)). (*See also* writing of Professor Gilbert "the fact that the settlement involves a payment from the patentee to the challenger is not sufficient to determine that the settlement is anti-competitive." (6 Tr. 1135 (Bresnahan)); (SPX 836).

Complaint Counsel's Response to Finding No. 3.311:

The proposed finding is irrelevant. CPRF 3.310

3.312. Thus, from an economic perspective net consideration in patent litigation should not be viewed as a "red flag" or a per se violation, even if a monopoly is involved. (29 Tr. 7298 (Willig). Nor is it facially anti-competitive conduct, meaning conduct that it is difficult to comprehend as being motivated by anything other than anti-competitive objectives or having anything other than an anti-competitive effects. (29 Tr. 7236 (Willig)

Complaint Counsel's Response to Finding No. 3.312:

The proposed finding is irrelevant. CPRF 3.310. Moreover, Professor Willig is not qualified to interpret legal terms like "per se" or "facially anti-competitive."

3.313. A theoretical economic model simply cannot be used to determine whether entry was delayed. (24 Tr. (Addanki) 5760-61, 5820). It is not clear that economic theory can reveal whether a payment would necessarily lead to an outcome that is later than the outcome under litigation. (24 Tr. 5761 (Addanki)). One cannot infer from the mere fact of a payment that entry was delayed beyond the likely date that would have occurred under litigation, nor, for that reason, can you infer that a net payment is facially anti-competitive. (24 Tr. 5795 (Addanki)). Such an

inference ignores many ways in which a settlement with a payment could result in a generic entry date that is earlier than the outcome likely under litigation. (24 Tr. 5761 (Addanki))

Complaint Counsel's Response to Finding No. 3.313:

The proposed finding is irrelevant. CPRF 3.310. To the degree Dr. Addanki has opined that an economic theory must predict with absolute certainty a result before it can be used, that opinion is contradicted by more reliable evidence. CPF 1341; 1222. The finding is contradicted by more reliable evidence. One can infer a payment was made for delay when the parties have the incentives to enter an agreement in which payment is given in consideration for delay, the evidence shows the parties acted on those incentives, and there is no other reason that justifies the payment. CPF 1186-1187 (parties had incentives to delay entry); 1188-1200 (parties acted on their incentives to reach an agreement to delay entry). Once it is shown that the payment was for delay, the settlement harms competition. CPF 1159-1160 (delaying entry harms consumers); 1166-1172 (delaying uncertain entry harms consumers); 1217-22 (settlement delays entry).

3.314. Both Complaint Counsel's economic expert, Professor Bresnahan, and its negotiations expert, Professor Bazerman, concede that negotiations may not even proceed according to a model of economic rationality. (6 Tr. 1141, 1142 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.314:

The proposed finding is irrelevant. CPRF 3.220.

3.315. These settlements should be analyzed under the only reliable standard as a matter

of policy – their impact on consumer welfare. (29 Tr. 7298-99 (Willig)). To determine whether an agreement with net consideration is anti-competitive one must make a direct analysis of all the evidence, in particular the underlying strength of the patent litigation. Even if it is too difficult to fully evaluate the merits of the patent litigation, one cannot rely upon the Bresnahan rule. "It's like saying I can't do the right analysis, so I'll embrace a wrong and dangerous analysis. That would be absolutely not the right way to go for policy." (29 Tr. 7234 (Willig)).

Complaint Counsel's Response to Finding No. 3.315:

The proposed finding is contrary to more reliable evidence. Although the respondent's experts posit that one must assess the patent probabilities and, based on that assessment, compare the settlement with the expected outcome of litigation, no economic expert testifying on behalf of the respondents attempted to assess the patent probabilities or compare the likely outcome of the litigation with the settlements. CPF 1303-04 (neither Professor Willig nor Dr. Addanki concluded that the settlement provided for an earlier entry date than the probable mean entry date under litigation). There is no evidence that one can reliably assess the objective probabilities of the patent case. CPF 1359. Professor Willig has never attempted the comparison he suggested, and he is not aware of anyone else performing this comparison. Tr. at 29:7300-04 (Willig). Professor Willig has never published research on assessing the objective probability of the patent litigation. Professor Willig is not aware of any research on whether or not an expert in the subject matter technology can arrive at an opinion about the odds of a particular side prevailing in a patent case. Tr. at 29:7304 (Willig). Professor Willig is not aware of research on whether the reliability of assessing the patent probability is affected by when,

in the litigation process, the case settles. Tr. at 29:7305.

Professor Willig agreed that if a comparison of the settlement date and the mean date of entry under litigation is not determined, one should consider other evidence to determine if the settlement is anti-competitive. Tr. at 29:7307 (Willig).

The finding is incomplete because knowing the patent probability would not allow one to determine whether a settlement in anti-competitive. One would need to know additional facts such as the expected growth or decline in the market place, the size of monopoly and duopoly profits, the size of the deadweight loss under monopoly and duopoly. These criteria cannot be measured reliably. CPF 1364-73.

The finding is irrelevant to the extent that it discusses a "Bresnahan Rule." Professor Willig misinterpreted Professor Bresnahan's analysis. Professor Willig describes Professor Bresnahan has concluding that there is delay solely from the fact of net consideration. Professor Bresnahan concluded that the payment was for delay based on (1) the parties incentives, (2) evidence that the parties acted on those incentives, and (3) no alternative justification for the payment. CPRF 3.226, *see also* 3.221.

3.316. Thus, the rule of reason is essential as a policy guide in this area of so-called reverse payments. (26 Tr. 6360 (Kerr)). Issues relevant to evaluating the net effect of whether the agreement is anti-competitive include determining whether the license agreement portion of the agreement is pro or anti-competitive, and whether the settlement of the litigation itself is pro or anti-competitive. (26 Tr. 6252 (Kerr)).

Complaint Counsel's Response to Finding No. 3.316:

The proposed finding is not a finding of fact. The application of the appropriate legal standard is a question of law. Similarly, what is entailed by the rule of reason is a legal conclusion, not a factual finding. Dr. Kerr has no expertise to comment on the meaning of the legal methodology known as the "rule of reason."

3.317. Complaint counsel's expert, Dr. Bazerman appeared to agree. Eschewing the Bresnahan net-consideration test, he concluded that we do not know what the world would have looked like without the settlement. To determine that, we would have to know who would have won the patent case or whether there would have been another settlement without a side deal. (36 Tr. 8607-08 (Bazerman)).

Complaint Counsel's Response to Finding No. 3.317:

This proposed finding is misleading, incomplete, and contradicted by more reliable testimony. The finding is misleading because the testimony does not address Professor Bresnahan's analysis of the agreement. Mr. Nields asked whether the existence of the settlement was the reason that there is generic competition today. Professor Bazerman responded,

> "I view what sounds like a simple question to be a complex question, because it's my understanding that there was a settlement that specified the entry date. We don't know what would have happened absent the agreement, so I need to know what the world would have looked like without the settlement to appropriately answer your question."

Tr. at 36:8608 (Bazerman).

In the context of answering Mr. Nields's question, a question that did not involve Professor Bresnahan's analysis, Professor Bazerman testified that he would have to know

what would have happened in the absence of the settlement. Tr. at 36:8608 (Bazerman). Professor Bazerman's testimony has nothing to do with what one must know to determine whether the agreement is anti-competitive.

The proposed finding is incomplete. Professor Bazerman agreed that, based on his expertise in negotiations and decision-making bias, none of those factors would change the conclusion that payment was for delay. Tr. at 36:8504 (Bazerman).

3.318. Professor Bresnahan has done nothing to evaluate the likely outcome of the litigation, and there is no way for him to answer the question of whether the settlement agreements at issue here resulted in entry dates that were later than could have been expected under litigation. (24 Tr. 5796-97 (Addanki)).

Complaint Counsel's Response to Finding No. 3.318:

The proposed finding is contrary to more reliable evidence. Professor Bresnahan concluded that the settlements at issue were anti-competitive based on standard economic principles. CPF 1129-1135. That analysis does not require one to assess the probabilities in the patent litigation. CPF 1171-72, 1338-44. Evaluating the probabilities in the patent litigation cannot be used in a reliable way to determine whether an agreement is anti-competitive. CPF 1345-73.

3.319. If agreements with net consideration were banned, there would be a negative impact on consumers by eliminating settlement agreements beneficial to consumers. (29 Tr. 7235 (Willig) Such agreements may be essential to break logjams and reach socially beneficial

agreements. (29 Tr. 7235 (Willig). A prohibition on such settlements would also result in businesses bearing undue risk and the costs of those risks, when such risks and costs could be avoided through a pro-consumer settlement of the underlying patent dispute. (29 Tr. 7235 (Willig).

Complaint Counsel's Response to Finding No. 3.319:

This proposed finding is contrary to more reliable evidence. There is no evidence that settlements with net consideration have been used to reach pro-competitive patent settlements. There is no evidence on the frequency of parties' being unable to settle based on the obstacles identified by the defendants experts. CPF 1415-1420. Generally, a payment of cash is not an effective tool to settle litigation. CPF 1421-24. Since most cases settle (CPF 1419) and reverse payments of net consideration are not seen in patent settlements generally (CPF 1415-1420), there is no basis in the record for a conclusion that prohibiting reverse payments would stifle socially beneficial settlements. At most, there are only a small number of cases that would be affected by such a payment. CPF 1426. Banning net consideration would chill settlements with parasitic integration (where the gains come from consumers) not settlements that create value. CPF 1427. Schering's own expert, however, leveled the same criticism at Professor Willig's requirement that one consider the merits of the patent suit. Tr. at 29:7121 (O'Shaughnessy).

C. PROOF OF ANTICOMPETITIVE EFFECT

1. Bresnahan Simply Infers Anticompetitive Effects from Incentives

3.320. Professor Bresnahan testified that a settlement is pro-competitive if the "percentage probability that the brand name would have won the patent" case is larger than the

"percentage of the remaining patent life during which the generic agreed to stay off the market." 6 Tr. 1211-12 (Bresnahan)). But, he has not undertaken on analysis of what the outcome of the litigations was likely to have been. (6 Tr. 1213 (Bresnahan)). He made no comparison of the entry date under the settlements with the probable entry dates had the litigating continued. Instead, he concluded the payment was for delay from a simple examination of the parties' incentives. (6 Tr. 1105 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.320:

The proposed finding is incomplete and misleading. Professor Bresnahan based his opinion that the payments were for delay on more than the parties incentives; he relied on multiple factors. *See* CPRF 3.221. As Professor Bresnahan explained: "The – I mean, that's not all that's here. The – here, there is not only the incentives but a contract in which there is a payment to the entrant." He did not assume "that everyone will break the law every time they have an economic incentive to do so." Tr. at 6:1106 (Bresnahan). Rather, he was doing what economist regularly do: rely on economic incentives when analyzing the impact of parties' actions. CPF 1186.

In addition, the excerpt from Tr. at 6:1211-1212 (Bresnahan) is incomplete and misleading. Even if one knew the patent probability, one would need to know multiple additional facts to determine the amount of competition allowed under a settlement that split the patent life. Discounting, additional entry, and changes in the market over time affect the calculation of how much competition is actually allowed under a settlement that allowed entry before the patent expires. *See* CPF 1367-1370. One could not just compare the percentage probability that the brand name would have won the patent suit

with the percentage of the remaining patent during which the generic agreed to stay off the market, as is suggested in the finding. The question cited explicitly assumed that adjustments were being made "to reflect the time value of money, any anticipated expansion or deterioration in the market for the brand name's drug over time, and any delay in entry for the generic that would have occurred even if it won the patent case." Tr. at 6:1212 (Bresnahan).

The proposed finding is also incomplete and misleading to the extent that it implies that one must assess the probabilities in the patent litigation to determine whether a settlement with a payment is anticompetitive. Professor Bresnahan applied a three-part test to the agreement to determine whether they delayed competition and harmed consumers. CPF 1129. The criteria the Professor Bresnahan applied are the standard criteria used by economists to determine whether an act is anticompetitive. Tr. at 3:418-419 (Bresnahan). One does not need to know the probability that the entrant would have won the patent suit to make this determination. CPF 1129 (identifying the criteria) and CPF 1171-1172, 1338-1344.

3.321. But Professor Bresnahan conceded that evidence that a person had an economic incentive to violate the law does not lead to the conclusion that they did so. (6 Tr. 1105 (Bresnahan)) In fact, most of the time people will not violate the law despite their incentive to do so. (*Id.*). This principle applies both to lawyers and businessmen for large companies. (18 Tr. 4077 (Bresnahan)). Professor Bresnahan also will not violate the law, even where there is a financial incentive to do so: he would not sell his own testimony to the highest bidder (6 Tr.

1107 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.321:

The proposed finding is irrelevant and misleading. The finding does not contradict or undermine Professor Bresnahan's conclusions that the agreements were anticompetitive because Professor Bresnahan relied on more than the parties' incentives to form his opinion. CPRF 3.320. Specifically, Schering and Upsher discussed the threat that Upsher's entry posed to Schering, assessed how much Upsher could earn, and agreed to a payment roughly equal to profits Upsher would have made had it won the patent law suit. These are the actions parties would take if they were acting on their incentives. CPF 1188-1200. Schering and AHP tied the money to how soon AHP would be a potential entrant, which is consistent with their acting on their incentives to delay entry. CPF 1209-1216.

How people may act in general is irrelevant to whether the parties here acted on their incentives to delay entry and harm competition.

Page 1105 of the record does not support the second sentence; however, complaint counsel assumes this is a typographical error and refers to page 1106. Page 4077 of the record does not support the third sentence; however, complaint counsel assumes this is a typographical error and the cite should be to page 1107.

3.322. Professor Willig testified that incumbents will not always give generics money in settlement that will push the date beyond the entry date under litigation, because wise incumbents

understand the antitrust risks. These risks will lead them to behave cautiously toward such settlements. (29 Tr. 7197 (Willig)). Antitrust economics looks at business or profit incentives to undertake unlawful conduct and balances that against the business decision-makers awareness of antitrust constraints. This can translate into procompetitive outcomes. There is no basis in economics for assuming that the incumbents will act in an anticompetitive manner. (29 Tr. 7197-92; 24 Tr. 6170 (Willig; Addanki). Professor Bresnahan testified that a settlement agreement is pro-competitive if the "percentage probability that the brand name *would have won the patent case*" is larger than the "percentage of the remaining patent life during which the generic agreed [under the settlement] to stay off the market." (6 Tr. 1211-12 (Bresnahan))

Complaint Counsel's Response to Finding No. 3.322:

The proposed finding is contrary to more reliable evidence. The respondents own economic justifications show that there are always anticompetitive settlements that the parties prefer over any procompetitive settlement. CPF 1228. None of the respondents' economists modeled any conditions under which a party would choose a procompetitive settlement it prefers less to an anticompetitive settlement it prefers more. CPF 1245. Incentives to obey the law can not apply to the varied assessment model or the misplaced optimism model. CPF 1254-1255.

Regardless of the proffered justification, the parties, under the standards proposed by the respondents, will not be able to distinguish a procompetitive settlement from an anticompetitive settlement. CPF 1256-1257. Under those circumstances, self-serving bias will lead the parties to reach anticompetitive settlements that they prefer more to procompetitive settlements that they prefer less. CPF 1258-1263.

The proposed finding is irrelevant because it only discusses incentives to obey the law but not the incentive identified by Professor Bresnahan, which is the incentive to increase joint profits by delaying the generic's entry.

Page 7197 of the record does support the second sentence of the finding. Complaint counsel assumes this is a typographical error, and it refers to page 7191.

3.323. The existence of economic incentives does not necessarily lead to anticompetitive conduct. (26 Tr. 6363 (Kerr)). Upsher had procompetitive incentives, including the incentive to obey the law, to get a proper return on its intellectual property, to enter the market in an effective way with Klor Con M10 and M20, and to get the litigation out of the way and move forward with running its business effectively. (26 Tr. 6364 (Kerr)).

Complaint Counsel's Response to Finding No. 3.323:

This proposed finding is incomplete. To the degree Dr. Kerr relies on incentives, his analysis has the same failings as respondents' other experts. *See* CPRF 3.322. The finding is misleading to the degree it implies that any of those incentives would counterbalance the incentive to delay. Dr. Kerr testified only that Upsher had these incentives; he did not testify that these incentives would nullify incentives to delay.

2. No Proof of Likelihood of Earlier Entry by Upsher-Smith

a. Upsher-Smith's chances of winning

3.324. Professor Bresnahan did not review the patent for K-Dur 20 to write his report or to prepare for his deposition, and he has no expertise in the strength or weakness of patent

claims. (4 Tr. 669 (Bresnahan)). In fact, he has not even reached an opinion as to whether the '743 patent is a valid patent, or as to whether Upsher actually infringed that patent. (4 Tr. 670 (Bresnahan)). The only evaluation he performed as to the strength of Schering's patent infringement claims were certain inferences he drew from the parties' economic behavior. (4 Tr. 671 (Bresnahan)). He cannot say, based on the facts as they were known in June 1997, whether there was more than a 50 percent chance that Upsher would enter before 2006. (4 Tr. 671-72 (Bresnahan)). Nor does Professor Bresnahan know who would have won the patent suit. (4 Tr. 671-72 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.324:

The proposed finding is irrelevant and incomplete. Professor Bresnahan also explained in considerable detail why the likely competitive effects of the agreements can be assessed without determining the likely outcome of the patent litigation. The full discussion of this point is found at CPF 1338-1344. To summarize briefly here: The economic analysis of whether an act harmed potential competition does not require knowledge of whether the uncertain competition would actually have occurred absent the anticompetitive act, and it does not depend on the reason for the uncertainty. If an incumbent and an entrant agree that the entrant will not market its product until a date in the future in exchange for compensation, it means that the parties believe that the agreement provides less competition than would happen in the absence of the agreement. Such an agreement is anticompetitive even if provides a certain entry date in the future, because that date provides less competition than what the parties (who had the best information available at the time concerning the amount of competition if the patent

litigation continued) expected to occur in the absence of the agreement. Moreover, as explained in CPF 1345-1363, the likely outcome of the either the Schering/Upsher or Schering/AHP patent litigation cannot reliably be predicted.

3.325. Professor Bresnahan testified that, he has *not* concluded that entry by Upsher-Smith "would definitely have occurred as of 1997." (4 Tr. 512-13 (Bresnahan)). Professor Bresnahan testified only that "uncertain entry is valuable to consumers." (4 Tr. 513 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.325:

The proposed finding is irrelevant and incomplete. Professor Bresnahan also testified that he interpreted the fact that Upsher and Schering were preparing for launch of a generic K-Dur 20 to mean they expected that there was a chance that entry would occur in the near term. Tr. at 3:512 (Bresnahan). Professor Bresnahan also testified that a contract that bars or delays uncertain competitive entry is anticompetitive, and why an incumbent firm and an entrant have incentives delay uncertain as well as certain competition. Tr. at 2:513-514 (Bresnahan); CPF 1161-1172. When analyzing whether an agreement harms competition, economists do not have to determine with certainty that entry would have occurred or that competition would have been successful. CPF 1341.

3.326. The evidence from the underlying patent litigation suggests that Upsher-Smith's chance of winning were less than 50 percent. Upsher-Smith's Phillip Dritsas testified that he

believed Upsher had less than a 50 percent chance of prevailing in the patent litigation with Schering. (Dritsas 4897) (*See also* Patent Finding at 3.642-3.643, 3.657-3.69, 3.671-3.672, 3.680, 3.683.

Complaint Counsel's Response to Finding No. 3.326:

The proposed finding is misleading and is contradicted by more reliable evidence. In fact, Mr. Dritsas testified that he had a "general understanding" that Upsher "didn't have better than a 50% chance of winning." Tr. at 20:4897 (Dritsas). Mr. Dritsas is Upsher's vice president of sales and marketing, and he not a patent lawyer. Tr. at 20:4612-4613. He gave no basis whatsoever for this statement. Indeed, both Schering and Upsher steadfastly refused to provide any information on their contemporaneous assessments of the likely outcome of the patent litigations, citing attorney client and work-product privilege. *See* Complaint Counsel's Motion and Memorandum in Support of Motion to Preclude Certain Testimony of Respondents' Lawyer Witnesses (Feb. 5, 2002). Moreover, the evidence in the record shows that Upsher vigorously contested whether its product infringed and whether Schering's patent was valid and enforceable. It prepared a comprehensive defense, obtained expert witnesses who were prepared to testify on its behalf, and filed a motion for summary judgment. [redacted] *See* CPF 98-117.

b. Timing of Upsher-Smith entry assuming it would have won

(1) Entry during litigation

3.327. Generic firms in the pharmaceutical industry typically do not enter the market when patent infringement litigation is pending. (26 Tr. 6259 (Kerr)). The FDA cannot grant approval under the Hatch-Waxman Act if patent infringement is alleged, so the generic cannot enter the market until: (1) the patent expires; (2) the patent is judicially determined to be invalid or noninfringed; or (3) 30 months has elapsed since litigation was initiated and the litigation has not concluded. (10 Tr. 2218 (J.F. Hoffman)). At the end of the 30-month stay of FDA approval pending Hatch-Waxman litigation, the FDA would not necessarily give final approval to the AB-rated generic, because of regulatory problems with the product. (27 Tr. 6735 (Kerr)). Further, the branded company can apply to the court to lengthen the 30-month stay in place during the pendency of the litigation. (27 Tr. 6735 (Kerr)).

<u>Complaint Counsel's Overall Response to Findings Nos. 3.327-3.332</u>:

The proposed finding are incomplete and are contradicted by more reliable evidence. All but one of these findings relates to the actions of companies other than Upsher. They are contradicted by the evidence, found in Upsher's contemporaneous business documents in this case, that Upsher not only took concrete steps to prepare for launch of its generic product during 1997 (CPF 125-138), [redacted]

The proposed findings are also irrelevant. The issue is whether Upsher or AHP were threats to Schering's monopoly. CPF 1131. Both Upsher and AHP were a threat to Schering's monopoly. CPF 1175, CPF §§ V, VIII. For example, Schering prior to the

Upsher settlement had withdrawn its field for K-Dur 20. Just two months after the settlement, however, Schering "[r]e-[l]aunch[ed] K-DUR 20 with field force." CX 20 at SP 004033. Schering wrote that it was relaunching the field force for K-Dur 20 because of "a new lease of life" for K-Dur 20. CX 20 at SP 004040. And, in the same document, written just after the Upsher settlement, Schering wrote that "the opportunity to grow sales to $300 million and beyond has been renewed." CX 20 at SP 004042.

Complaint Counsel's Specific Response to Finding No. 3.327:

The proposed finding is incomplete. There is no evidence that Schering applied to the district court to lengthen the 30-month stay, as it might have done; instead, it reached a settlement with Upsher. Upsher's product received final FDA approval on November 20, 1998, well before the September 1, 2001 entry date established in the Schering/Upsher Agreement. CPF 165.

3.328. Even if a generic has received approval, and it could enter the market during the appeal of a pending patent litigation, it is very unlikely a generic would enter the market if it perceived it had a risk of losing an appeal. (26 Tr. 6260 (Kerr)). If it did enter, a generic firm would face an "intolerable" risk of being found later to infringe and facing damages likely to be far in excess of what they would stand to earn entering the market. (26 Tr. 6260-61 (Kerr)).

Complaint Counsel's Response to Finding No. 3.328:

The proposed finding is incomplete. Dr. Kerr testified that the risk faced by a generic firm would be intolerable "in most instances." Tr. at 26:6260 (Kerr), and he was not referring specifically to the situation Upsher faced in early 1997. In fact, he testified

that he did not do any specific analysis of the probability that Upsher would prevail in the Schering/Upsher litigation. Tr. at 26:6264-65 (Kerr); CPF 1387. *See* CPRF 3.327-3.332 (overall).

3.329. This was confirmed by complaint counsel's witness, Mr. Rosenthal. Andrx currently is not marketing its potentially most lucrative product, a generic of AstraZeneca's Prilosec, despite the expiration of this 30-month stay. (8 Tr. 1576-77 (Rosenthal)). Andrx is still in litigation with AstraZeneca over Andrx's alleged patent infringement and therefore marketing the drug is "too risky at this stage." (8 Tr. 1580-81 (Rosenthal)). Andrx chooses to stay off the market. (8 Tr. 1585 (Rosenthal)). Indeed, if Andrx were to enter the market and then lose the patent infringement case, it could be subjected to substantial treble damages. (8 Tr. 1581 (Rosenthal)).

Complaint Counsel's Response to Finding No. 3.329:

See CPRF 3.327-3.332 (overall).

3.330. Mr. Rosenthal is aware of numerous situations in which companies have not gone to market with their generic alternative even though they have FDA approval, simply because the risk during pending litigation is too high. (8 Tr. 1583 (Rosenthal)).

Complaint Counsel's Response to Finding No. 3.330:

See CPRF 3.327-3.332 (overall).

3.331. Mr. Kralovec believed that it would be "financial suicide" to launch Klor-Con

M20 before the resolution of the Schering-Upsher patent litigation. (21 Tr. 5038 (Kralovec)). It was Mr. Kralovec's understanding that if Upsher ended up losing the litigation, it may have to pay significant damages related to marketing its infringing product. (21 Tr. 5038 (Kralovec)).

Complaint Counsel's Response to Finding No. 3.331:

The proposed finding is incomplete. Upsher's contemporaneous documents show that Upsher considered various launch scenarios for 1997, some of which assume launch after the trial and others after the trial and appeal. In these scenarios, January 1, 1998 was considered the latest possibility. CPF 125-128. Mr. Kralovec himself testified that in May 1997, Upsher was considering launching Klor Con M20 in late 1997 or early 1998. Tr. at 21:5086 (Kralovec); CPF 129.

3.332. Upsher anticipated that Klor Con M would be approvable as of the end of 1996, and when that occurs, the pendency of the lawsuit would prevent Upsher-Smith from introducing Klor Con M to the marketplace (CX 1731) [redacted] This statement is consistent with Upsher's attitude that it was not realistic to come to market while the lawsuit was pending. (28 Tr. 6902 (Kerr)).

Complaint Counsel's Response to Finding No. 3.332:

The proposed finding is contradicted by more reliable evidence in the record. [redacted]

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3.333. Dr. Kerr's consulting group maintains a database on patent infringement suits from between 1990-2001 that collects information from district court and Federal Circuit patent decisions about how the court applied economic principles with respect to damages, product definitions, and reasonable royalties. (26 Tr. 6243-44 (Kerr)). In his analysis, Dr. Kerr also used a database maintained by the Administrative Office of the U.S. Courts that contains information on all civil cases filed in the U.S. (27 Tr. 6702 (Kerr)). Dr. Kerr separated out the patent cases from the other civil cases, and he believes there are around 10,000 patent cases in the database. (27 Tr. 6703 (Kerr)).

Complaint Counsel's Response to Finding Nos. 3.333- 3.337:

The proposed findings are irrelevant and are not supported by the evidence. As was demonstrated in CPF 1378-1404, Dr. Kerr's model of litigation outcome is based on assumptions that are not applicable to the Schering/Upsher patent litigation, and as a result, it cannot accurately predict the expected date at which the patent litigation would have concluded. In fact, it was not intended to predict the date when the patent litigation would be over, but only to illustrate when the litigation would be expected to be completed, on average. CPF 1382. The model is not based on the particular facts an circumstances of the Schering/Upsher litigation; Dr. Kerr did not make any effort to assess the probability that Upsher would prevail in the patent litigation. CPF 1387. Moreover, the model does not predict that Upsher could not have entered the market earlier than September 1, 2001. Dr. Kerr simply assumed that Upsher would not enter

until the conclusion of the patent litigation, but he was not aware of the representations that Upsher made to the judge in the patent case regarding its readiness to enter the market, and his model does not take into account the actions that Upsher was taking to enter the market before the suit was settled. CPF 1398-1404.

The model is fragile and incorrect. It is fragile because it does not make any attempt to assess the relative value of the early years as opposed to the later years in the patent. If Dr. Kerr had accounted for the change in value of the patent over time, it would change his answer. The model is also flawed because Dr. Kerr assigns zero probability to Upsher entering within 19 months of the settlement even though that contradicts the views of the managers at Upsher. CPF 1404.

3.334. In the patent cases Dr. Kerr analyzed, an average of nineteen months elapses from the date of a final judgment in the district court to a final decision on appeal. (26 Tr. 6265 (Kerr)).

Complaint Counsel's Response to Finding No. 3.334:

In addition to the general criticism, *see* CPRF 3.333- 3.337 (overall), Dr. Kerr's data set has only cases with damage claims. CPF 1385. Because the Schering/Upsher litigation had no damage claims, this statistic is unreliable and does not accurately predict the outcome of the timing of the Schering/Upsher litigation. Therefore, Dr. Kerr's opinion on the timing of the outcome of Schering/Upsher litigation is unreliable.

3.335. Thirty-six percent of cases are remanded by the Federal Circuit to the district

court for further action. (*Id*).

Complaint Counsel's Response to Finding No. 3.335:

This statistic is unreliable and does not accurately predict the outcome of the timing of the Upsher-Schering litigation is unreliable. CPRF 3.334; *see also* CPRF 3.333- 3.337 (overall).

3.336. Based on this analysis, Dr. Kerr's conclusion is that the settlement date of September 2001 accelerated Upsher's entry date by 17 months. (26 Tr. 6274 (Kerr); (USX 1596). This analysis does not account for regulatory approval or manufacturing ramp-up. (26 Tr. 6275 (Kerr)).

Complaint Counsel's Response to Finding No. 3.336:

The proposed finding is misleading. Dr. Kerr's testimony was that the settlement accelerated Upsher's "potential" entry date, as compared to the time, on average, when the litigation could be expected to be finished. He did not predict an actual entry date for Upsher. Tr. at 26:6274-6275 (Kerr).

3.337. As a result, the settlement provides more competition than continued litigation would have. (26 Tr. 6275 (Kerr)).

Complaint Counsel's Response to Finding No. 3.337:

The proposed finding is misleading. Dr. Kerr compared the entry date under the settlement agreement to the predicted date of conclusion of the litigation based on the

average outcome of patent cases. He did not predict when the Schering/Upsher litigation actually would have been finished. Tr. at 26:6274-6275 (Kerr).

3.338. Professor Bresnahan has not modeled how long litigation would have lasted, including appeals. (5 Tr. 904 (Bresnahan)). He has looked at internal company estimates, but is aware that these estimates could be wrong. (5 Tr. 904-05 (Bresnahan)). Nor did Professor Bresnahan perform any analysis of how long Upsher might have been able to sustain its defense of the patent infringement suit in this case. (4 Tr. 665 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.338:

The proposed finding is incomplete. As was stated in greater detail in CPRF 3.324, Professor Bresnahan explained why the likely competitive effects of the agreements can be assessed without determining the likely outcome of the patent litigation. CPF 1338-1344. In addition, the last sentence of the finding is misleading because it ignores the direct evidence in the record that Upsher was financially able to sustain its defense of the patent infringement suit. CPF 1318-1326 (••••••••••••••••••••••••••••••).

3.339. Complaint counsel's patent litigation expert, Professor Adelman, testified that proceedings in the district court could have taken as long as five years. (32 Tr. 7773-74 (Adelman)). And he also testified that the Federal Circuit could have taken an additional three years to decide the case. (*Id.*). Mr. Adelman has testified as a law expert in patent cases over 150 times. (32 Tr. 7703 (Adelman)).

Complaint Counsel's Response to Finding No. 3.339:

This finding is misleading and not supported by the evidence. Mr. Adelman did not testify on how long the Schering/Upsher litigation was likely to take at the district court or at the court of appeals. He said only that district courts could take five years, and he was not asked about the length of time from trial to a decision. As to the court of appeals, he said only that he was aware of cases in the Federal Circuit taking three years.

The prosed finding is incomplete. The projections made by Upsher employees during 1997 projected a much earlier conclusion of the litigation. CPF 125-129.

(2) Entry after litigation

3.340. It took the Upsher approximately 2.5 years to prepare for the launch, which was by far the biggest launch that Upsher has ever had. (21 Tr. 5116 (Gould); 23 Tr. 5483-88 (Troup); 21 Tr. 5042-49 (Kralovec); 21 Tr. 5124-61 (Gould); 26 Tr. 6369-70 (Kerr)). The launch took so long because of the very large volume of tablets, around 100 million, needed to be ready for the launch. 21 Tr. 5116 (Gould).

Complaint Counsel's Response to Findings Nos. 3.340-3.342:

The proposed findings are not relevant to whether or when Upsher could have launched its generic version of K-Dur 20 absent the Schering/Upsher Agreement in June 1997, and they are contradicted by more reliable evidence. Before the Schering/Upsher Agreement, Upsher was preparing to enter the market in the near future. All during the time period, late-1996 through May 1997, Upsher took the following actions preparing for launch: [redacted]

[redacted]; (2) projected dates for entry between August 1997 and January 1998 (CPF 125-28); (3) engaged in marketing-related preparations, including analyzing the market and projecting launch quantities (CPF 130-131); and (4) scheduled validation batches at IPC for June 1997 and reserved time at IPC for production in August of launch scale quantities of Klor Con M20 (CPF 132, 136-139).

The proposed findings are irrelevant. The issue is whether Upsher or AHP were threats to Schering's monopoly. CPF 1131. Both Upsher and AHP were a threat to Schering's Monopoly. CPF 1175, CPF §§ V, VIII. For example, Schering prior to the Upsher settlement had withdrawn its field force for K-Dur 20. Just two months after the settlement, however, Schering "[r]e-[l]aunch[ed] K-DUR 20 with field force." CX 20 at SP 004033. Schering wrote that it was relaunching the field force for K-Dur 20 because of "a new lease of life" for K-Dur 20. CX 20 at SP 004040. And, in the same document written just after the Upsher settlement, Schering wrote that "the opportunity to grow sales to $300 million and beyond has been renewed." CX 20 at SP 004042.

Complaint Counsel's Response to Finding No. 3,340:

The proposed finding is not relevant to whether or when Upsher could have launched its generic version of K-Dur 20 absent the Schering/Upsher Agreement in June 1997, and it is contradicted by more reliable evidence. Changed circumstances in 1999 compared to those in 1997 make the events leading up to the 2001 launch of Klor Con

M20 irrelevant to the possibility that Upsher could have launched that product in 1997. The K-Dur 20 market grew between 1997 and 1999. CPF 157. Upsher also looked at various launch scenarios and changed its launch strategy. CPF 158-159. As a result of these two factors, by May 1999, Upsher decided it would need 90-100 million Klor Con M20 tablets to launch in September 2001, as compared to the 28.2 million it projected were needed in1997. CPF 156, 160. This requirement for more tablets than was needed in 1997 caused Upsher to have to increase the capacity of its manufacturing capabilities and those of its contract manufacturer, IPC. CPF 161.

3.341. Upsher wanted plenty of time to prepare for the launch. (21 Tr. 5118 (Gould)). Having a certain date of entry under the Settlement agreement allowed Upsher-Smith to prepare for its eventual launch. (21 Tr. 5116 (Gould)).

Complaint Counsel's Response to Finding No. 3.341:

The proposed finding is not relevant to whether or when Upsher could have launched its generic version of K-Dur 20 absent the Schering/Upsher Agreement in June 1997, and it is contradicted by more reliable evidence. After the Schering/Upsher Agreement, Upsher prepared to launch in September 2001. Between 1997 and 1999 it did little or no work on preparing to launch Klor Con M20. CPF 150-151. It began preparing in May 1999 and purposefully allowed itself over two years to launch, simply using its then available time. CPF 152-154.

3.342. The time to prepare its generic for launch made Upsher-Smith a more effective

competitor. In September 2001, Upsher actually delivered $28 million worth of Klor Con M20. (18 Tr. 4872 (Dritsas)). Today the sales are over $60 million. (18 Tr. 4872 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.342:

The proposed finding is not relevant to whether or when Upsher could have launched its generic version of K-Dur 20 absent the Schering/Upsher Agreement in June 1997, and it is contradicted by more reliable evidence. Upsher was preparing to enter the market at the time of the Schering/Upsher Agreement, and it and IPC had the ability to manufacture and launch Klor Con M20. CPF 119-162. To produce and have ready for launch the 28.2 million tablets Upsher projected, in April 1997, that it would need to go to market, would have taken only between sixteen and twenty-two weeks. CPF 145-147.

3. No Proof of Likelihood of Earlier Entry by ESI

3.343. In July 2001, American Home Products announced its intention to exit the oral generics business. (Stipulation Dated Jan. 16, 2002; CX 1548 at 45:21-25 (Dey Depo.)).

Complaint Counsel's Response to Finding No. 3.342:

The proposed finding is not relevant to whether or when AHP could have launched its generic version of K-Dur absent the Schering/AHP agreement. AHP had developed a generic product (CPF 814-815), there was a possibility that AHP would win the infringement lawsuit (CPF 821-840), and there was sufficient possibility that AHP could have entered the market with its generic product to provide Schering with an incentive to pay AHP not to compete. CPF 74-82 (Schering anticipated early generic

entry by AHP, among others); it was a potential generic entrant and a threat to Schering's monopoly power (CPF 845); CPF 901-931 (uncertainty about 180-day exclusivity); CPF 1209-1216 (Schering paid AHP to delay its entry).

4. Potential Anticompetitive Effects From Generic Entry

3.344. Under certain circumstances, the entry of a generic product can diminish certain dimensions of competition. (Addanki 5950-52; 6169). One therefore needs to balance any enhancement in competition in certain dimensions of competition with diminutions in competition in other dimensions when evaluating the effect of generic entry. (Addanki 5819-21). One must determine how an increase in one dimension of competition nets out with the decrease in another dimension of competition. (24 Tr. 5759-60 (Addanki 5819-21)).

Complaint Counsel's Response to Finding No. 3.344:

The finding is contrary to more reliable evidence. Economists believe that competition is generally good for consumers. Tr. at 34:8062 (Bresnahan); *see also* Tr. at 3:424-25 (Bresnahan) (using demonstrative CX 1568 (pie chart) to illustrate how consumers benefit from competition). Any assertions that entry by a competitor into a market may harm consumers is viewed highly skeptically by economists. Such assertions would require significant evidence before being accepted. Tr. at 34:8062 (Bresnahan).

Dr. Addanki, however, provided no evidence that the entry of generic K-Dur has harmed consumers. Tr. at 34:8062 (Bresnahan). He provided no examples where generic entry has harmed consumers. Tr. at 34:8062-63 (Bresnahan). He cited no articles that showed generic entry harmed consumers. Dr. Addanki relies only on a single article,

which is one of the first articles in the economic literature on this subject, and it only raised the question of whether entry could harm consumers. Tr. at 34:8063 (Bresnahan).

This question has since been settled by subsequent articles, and economists have concluded that generic pharmaceutical entry benefits consumers. Tr. at 34:8059-60 (Bresnahan). Dr. Addanki's position contradicts the position taken by economists generally.

Dr. Addanki's position also contradicts the economic principles on which the Bureau of Labor Statistics (BLS) relies in measuring the Pharmaceutical Price index. Previously, the BLS treated generic entry as a new good, so the entry did not cause a decline in the Pharmaceutical Price Index. Around 1994, the BLS began recording the new generic products as a "quality-adjusted price fall." Tr. at 34:8060 (Bresnahan). Similarly, in measuring the Consumer Price Index, the BLS treats generic entry as a "quality-adjusted price fall." Tr. at 34:8059 (Bresnahan). The BLS measures its price indexes like the Consumer Price Index from a consumer welfare perspective. Tr. at 34:8060 (Bresnahan). The BLS's treatment of generic entry as a quality-adjusted price decrease is inconsistent with Dr. Addanki's position that generic entry may harm consumers. Tr. at 34:8060-61 (Bresnahan); *compare* Tr. at 24:5897-98 (Addanki) (suggesting generic entry may not lead to a quality-adjusted price decline).

Dr. Addanki's opinion that generic entry might harm consumers leads to absurd results. If generic entry did harm consumers, it would justify any conduct that prevented entry; for example, if there were no patent dispute, a finding that consumer welfare harmed consumers would still justify a brand paying a generic not to enter. Tr. at

34:8063-64 (Bresnahan).

3.345. Promotion is an important dimension of competition. It would be a cause of concern, for instance, if two firms with monopoly power colluded to eliminate promotions from the market. (24 Tr. 5808 (Addanki), referencing *California Dental Association v. FTC*, 526 U.S. 756 (1999). A study by Ernst Berndt and others that was published in Professor Bresnahan's book, *The Economics of New Goods*, concludes that "marketing plays a very significant role" as an instrument for competitive rivals. (USX 1009); 4 Tr. 881 (Addanki); CX 72, USL 142602.)).

Complaint Counsel's Response to Finding No. 3.345:

The finding is irrelevant. Generic entry benefits consumers, and this is well-accepted amongst economist and policy-makers. CPRF 3.344.

3.346. Once Upsher's M20 product entered the market in September 2001, the mandatory substitution of some states' required a pharmacist to fill a K-Dur 20 prescription with the generic, effectively blocking K-Dur from competing for this patient segment. (20 Tr. 4824-25 (Dritsas)).

Complaint Counsel's Response to Finding No. 3.346:

The finding is contradicted by other evidence. A patient or physician can refuse substitution and continue to purchase K-Dur.

In states with such "mandatory" substitution laws, the patient generally is permitted to refuse the generic and purchase the brand name drug instead, even if the

prescriber does not direct the pharmacist to dispense the prescription as written. *See, e.g.*, Minn. Stat. § 151.21 ("the pharmacist shall, after disclosing the substitution to the purchaser, dispense the generic drug, *unless the purchaser objects*."); 35 P.S. § 960.3 ("the pharmacist shall substitute a less expensive generically equivalent drug *unless requested otherwise by the purchaser or indicated otherwise by the prescriber*."); W. Va. Code § 30-5-12b ("The person presenting the prescription *shall have the right to refuse the substitution*."); Mass. Law ch. 112, § 12D ("at the bottom of the prescription form, shall be printed these words: 'Interchange is mandated *unless the practitioner writes the words no substitution in this space*'"); Miss. Code § 73-21-117 ("A pharmacist shall select a generic equivalent product" *when such a request is made by the purchaser, the physician has not expressly prohibited substitution*, and the substitution will yield lower costs to the purchaser); NY CLS Educ § 6816-a ("A pharmacist shall substitute a less expensive drug product containing the same active ingredients, dosage form, and strength as the drug product prescribed" *when the prescriber does not expressly prohibit substitution*, the substitute is found in the Orange Book, and the pharmacist records the substitution on the label and on the prescription form); 35 P.S. § 960.3 ("the pharmacist shall substitute a less expensive generically equivalent drug unless *requested otherwise by the purchaser* or indicated otherwise by the prescriber"); R.I. Gen. Laws § 5-19.1-19 ("Pharmacists when dispensing a prescription shall, *unless requested otherwise by the individual presenting the prescription in writing*, substitute drugs containing all the same active chemical ingredients of the same strength, quantity, and dosage form as the drug requested by the prescriber from approved prescription drug products"). (*emphasis*

added).

The finding is contrary to more reliable evidence. Schering does compete with generics by launching its own generic and lowering price. CPF 989, 1115.

3.347. Schering stopped promotion of K-Dur 20 based on the anticipated entry of Upsher-Smith's Klor Con M20. (SPX 2089) (demonstrative); (24 Tr. 5804 (Addanki)). Schering stopped promoting because it would no longer receive a return from that promotion. (Addanki 5803-04). When the brand manufacturer promotes and advertises its brand, the brand awareness of that drug increases. (Bresnahan at 651). It makes physicians more likely to prescribe that drug. (Addanki 5801). When an A-B rated generic enters the market, continued promotion may get physicians to continue writing prescriptions, but the generic drug gets dispensed rather than the branded drug that was prescribed. (Addanki 5800-01) (Dristas 4824-25). Consequently, the branded manufacturer has very little incentive to continue promotion. The benefits of the promotion go to the generic manufacturer instead of the branded manufacturer. (Addanki 5801). That eliminates branded manufacturers' incentives to promote. (24 Tr. 5801 (Addanki)).

Complaint Counsel's Response to Finding No. 3.347:

The finding is not relevant. Generic entry benefits consumers, and this is well-accepted amongst economists and policy-makers. Schering's economist who sponsored this theory produced no evidence or even examples that a reduction in promotion caused by generic entry has harmed consumers. Tr. at 34:8062-63 (Bresnahan). *See* CPRF 3.344.

3.348. Generic entry thus undermines the value of the brand, which the company has built over time. (24 Tr. 5868 (Addanki)). Brands have value, because there is an investment in their development. (24 Tr. 5870 (Addanki)).

Complaint Counsel's Response to Finding No. 3.348:

The finding is not relevant. Generic entry benefits consumers, and this is well-accepted amongst economists and policy-makers. Schering's economist who sponsored this theory produced no evidence or even examples that a reduction in promotion caused by generic entry has harmed consumers. Tr. at 34:8062-63 (Bresnahan). *See* CPRF 3.344.

The finding is further irrelevant because there is no evidence that building the value of a brand benefits consumers or that competition reducing the value of the brand harms consumers. Competition that reduces monopoly power always reduces the value of the monopolist's product. CPF 1151 (By reducing incumbent's monopoly profits, competition creates consumers savings).

3.349. If pioneer firms continue to promote the brands, generics would be able to free ride on the brand's value. (24 Tr. 5870-71 (Addanki)). Thus, when a generic product enters the market, the level and amount of promotion and advertising that a brand name company performs for a given brand product declines. (1 Tr. 264 (Teagarden)).

Complaint Counsel's Response to Finding No. 3.349:

The finding is not relevant. Generic entry benefits consumers, and this is well-accepted amongst economists and policy-makers. Schering's economist who sponsored

this theory produced no evidence or even examples that a reduction in promotion caused by generic entry has harmed consumers. Tr. at 34:8062-63 (Bresnahan). *See* CPRF 3.344.

3.350. This has occurred before in the potassium chloride market. When Ethex, an AB-rated generic to Wyeth's Micro-K, entered the market in 1987, Wyeth sharply reduced its promotion of Micro-K. (24 Tr. 5802 (Addanki)). KV Pharmaceuticals, the owner of Ethex, later bought Micro-K, thus bringing into common ownership Micro-K and its generic equivalent, Ethex. (24 Tr. 5803 (Addanki)). This gave KV a renewed incentive to promote the brand product again, because prescriptions written for Micro-K would benefit KV Pharmaceuticals whether they were written for Micro-K or for Ethex. (SPX 2286) (demonstrative) (24 Tr. 5802-03 (Addanki)). The renewed promotions resulted a substantial sales increase for Ethex. (Addanki 6153) (CX 1713).

Complaint Counsel's Response to Finding No. 3.350:

The finding is incomplete and misleading. Dr. Addanki's opinion on the KV merger is unreliable. Dr. Addanki formed his opinion without reviewing the advertising by K-V. Dr. Addanki did know how much of the KV advertising was promotional or informational. Tr. at 25:6128 (Addanki). Dr. Addanki could not remember the date of the KV acquisition. Tr. at 25:6128 (Addanki) (late '98 or early '99). Therefore, his opinion that Ethex's sales increased after the merger are suspect. For example, Dr. Addanki admitted that in March 1999 Ethex units were 40 million and in December they were 39 million, which contradicts his opinion that sales increased for Ethex.

His opinion is unreliable because he did not consider whether the KV merger

actually harmed competition by increasing prices. Moreover, although Dr. Addanki has not reviewed the merger, the KV story demonstrates the competitive harm that can occur by delaying the unique price competition that is provided by a product that is AB-rated to a competing brand. According to Dr. Addanki's own data, KV was able to substantially increase Ethex 10 prices, despite facing competition from other BC-rated 10 mEq potassium chloride products, because it lacked an AB-rated competitor (which, in effect, the acquisition had eliminated by removing KV's closest competitor). [redacted] Within two years of the acquisition, Dr. Addanki's data shows that Ethex 10 prices went up by 100 percent, while Micro-K 10 prices went up by 50 percent. Prior to the acquisition, Ethex 10 prices had been on a slight downward trend. Tr. at 25:6128-33 (Addanki).

Delayed entry of Klor-Con M20 delayed the unique price competition that would have been provided by the only AB-rated competitor to K-Dur 20. Indeed, the consumer welfare harm from delaying entry of a generic version of K-Dur 20 is far greater than that which occurred for the Micro-K and Ethex products. K-Dur 20 accounted for more than $200 million in net sales in 2000 whereas the Micro-K and Ethex products combined for less than $50 million in net sales in 2000. *See* CX 34 at SP 020652-53. Moreover, K-Dur 20 faced no 20 mEq tablet or capsule competitors until the introduction of Klor-Con M20 and accounted for 65 to 70 percent all potassium chloride dollar sales between 1998 and 2000. *See* Addanki Tr. at 25: 6006-8; CX 34 at SP 020635, SP 020644, SP 020652.

By contrast, Micro-K and Ethex products accounted for less than 15 percent of all potassium chloride dollar sales during that same period. *See* CX 34 at SP 020635-36, SP 020644-45, SP 020652-53. *See* CPRF 3.345.

3.351. The loss of Schering's K-Dur promotion harms consumers not only because of the loss of one dimension of competition. It also harms consumers because most of Schering's advertising is informative. (25 Tr. 6120 (Addanki))). For example, Schering provided free samples for patient use, educated physicians and focused them on hypokalemia. (SPX 2091) (demonstrative) (24 Tr. 5804-09 (Addanki)). Schering also provided compliance aids for patients. (24 Tr. 5086 (Addanki)) (SPX 2092) (demonstrative). Schering's advertisements also informed patients and physicians about the importance of treating and preventing hypokalemia and warned patients who were taking diuretics about the risk of hypokalemia and about the importance of compliance with dosing. (24 Tr. 5807 (Addanki)) (SPX 2093) (demonstrative). Such information is valuable to patients and physicians and may not be readily available from other sources. (SPX 2093) (demonstrative); (24 Tr. 5806 (Addanki)).

Complaint Counsel's Response to Finding No. 3.351:

The finding is not relevant. Schering's economist who sponsored this theory produced no evidence or even examples that a reduction in promotion caused by generic entry has harmed consumers. Tr. at 34:8062-63 (Bresnahan). *See* CPRF 3.345, 3.351. Informative advertising benefits the category while persuasive advertising shifts demand from one product to another. Tr. at 25:6113-14 (Addanki). Only informative advertising improves consumer welfare. Tr. at 25:6113 (Addanki).

Dr. Addanki's opinion that most of Schering's advertising is informative is unreliable. Dr. Addanki did not look at the actual ads, yet he is opining on the content of those ads. Tr. at 25:6115-16 (Addanki). Nor did Dr. Addanki perform an econometric analysis to determine how much of Schering's advertising was informative and how much was persuasive. Nor did Dr. Addanki explain how he measured the amount of informative and persuasive advertising.

The documents Dr. Addanki testified about provide no basis for his opinion that most of Schering's advertising was informative. Dr. Addanki did not explain how providing a free sample is informative and not persuasive marketing. In the same documents, Schering also discussed persuasive advertising. CX 18 at SP 23 00050, 52, 53, 57-58 (1997 Marketing Plan) (Targeting high prescribers of potassium)(target audience patients receiving potassium replacement therapy)("Additionally, our message will be included with competitive product prescriptions (i.e. generic potassium) and may convert business to K-Dur 20 mEq)(campaign on the benefits of the 20 mEq over the 10 mEq).

3.352. Schering observed that "market research shows that patients with a thorough understanding of why they are taking their potassium tend to be more compliant." Hence, "physicians, pharmacists, and patients need to be educated on the seriousness of hypokalemia." Schering therefore offered "[P]atient education pieces on the dangers of hypokalemia for physicians and pharmacists are developed and implemented." (CX 140 SP 00002. *See also* CX 140 SP 00006 ("Implement programs to increase importance of K-DUR as treatment for serious

consequences of Hypokalemia. Utilize Schering CMI program (Compliance Management Initiative).")

Complaint Counsel's Response to Finding No. 3.352:

The finding is not relevant. Generic entry benefits consumers, and this is well-accepted amongst economists and policy-makers. Schering's economist who sponsored this theory produced no evidence or even examples that a reduction in promotion caused by generic entry has harmed consumers. Tr. at 34:8062-63 (Bresnahan). *See* CPRF 3.344.

The finding is not relevant to assessing how much of Schering's advertising was informative versus persuasive. Schering employed persuasive advertising. CPRF 3.351, 3.353.

3.353. One Schering document makes clear how important Schering's promotions were to expanding the market: "Past market research has shown that patients are unaware of the importance of potassium replacement therapy. Physician attitude toward potassium replacement is a major contributing factor. A combined effort using field sales representatives in combination with clinical and public relations activities will lead to increased awareness of the importance of potassium. *The result will be an expansion of the potassium market* to complement growth in market share of K-DUR." (SPX-902), (emphasis added).

Complaint Counsel's Response to Finding No. 3.353:

The finding is irrelevant to determining the impact of the specific agreements at issue in this case. Generic entry benefits consumers, and this is well-accepted amongst economists and policy-makers. Respondents have produced no evidence that consumers

will be harmed by loss of promotion or that the size of the overall industry fell as a result of the entry of generic 20 mEq tablets. *See* CPRF 3.344.

The finding is not relevant to assessing how much of Schering's advertising was informative versus persuasive. The very same documents lists a series of communications points, all of which deal with the benefits of K-Dur 20 as a unique potassium supplement product. SPX 902 at 23 00080. Similarly, in the 1998 marketing plan, Schering want to "continue to use its status as the only 20 mEq potassium replacement and its safety and convenience to dominate the market." Its message strategy was to "Develop physician-driven promotional rational supporting the advantages of K-Dur 20 mEq for use with high-potential called-on physicians."

Other evidence shows that Schering's promotion had little effect on the sales of all potassium chloride supplements. *See* CPRF 3.355.

3.354. Indeed, expanding the oral potassium chloride supplement market was a key strategy for Schering. Schering expanded the market by "Energiz[ing] the potassium market by establishing aggressive and credible guidelines for potassium replacement therapy," and by "Expand[ing] appropriate use of potassium replacement therapy by providing new insights into the clinical importance of maintaining serum K levels, particularly in patients at high risk." (SPX-1124)

Complaint Counsel's Response to Finding No. 3.354:

The finding is irrelevant to determining the impact of the specific agreements at issue in this case. Generic entry benefits consumers, and this is well-accepted amongst

economists and policy-makers. Respondents have produced no evidence that consumers will be harmed by loss of promotion or that the size of the overall industry fell as a result of the entry of generic 20 mEq tablets. *See* CPRF 3.344.

The finding is not relevant to assessing how much of Schering's advertising was informative versus persuasive. On the very page cited in the proposed finding, Schering also had a heading entitled "Grow Market Share," in which Schering wanted to redirect it sales force "to ensure growth of market share for K-Dur 20." SPX 1124 at SP 23 00121. Moreover, Schering budgeted $3.35 million for expanding share and combat generic competition and only $1.25 million for expanding the market. *Compare* SPX 1124 at SP 23 00149-50 *with* SPX 1124 at SP 23 00148.

3.355. Accordingly, the Schering promotions stimulated demand for oral potassium chloride supplements because they conveyed the informational messages about compliance, dosage maintenance, and the dangers of hypokalemia. (25 Tr. 6118; 24 Tr. 5804 (Addanki)). K-Dur was a "major products driving [the] increase in the Potassium Chloride Market." (SPX-1110).

Complaint Counsel's Response to Finding No. 3.355:

The finding is irrelevant to determining the impact of the specific agreements at issue in this case. Generic entry benefits consumers, and this is well-accepted amongst economists and policy-makers. Respondents have produced no evidence that consumers will be harmed by loss of promotion or that the size of the overall industry fell as a result of the entry of generic 20 mEq tablets. *See* CPRF 3.344.

The proposed finding is contrary to more reliable evidence. Dr. Addanki asserted that the promotional advertising of Schering increased demand for all potassium chloride supplements, but he never explained his basis for his conclusion that Schering's advertising, as opposed to some other cause, increased the demand for all potassium chloride products. The cited document (SPX 1110) does not discuss or mention Schering's promotions in connections with the cited excerpt.

Other evidence is directly contrary to Dr. Addanki's assertion. In the backgrounder to the cited document, Schering wrote "the overall market is not growing as expected." Throughout 2001, Dr. Addanki admitted that total prescriptions for potassium chloride sales continued to increased. Tr. at 25:6125 (Addanki); this trend occurred despite the fact that Schering had cut its promotional expenditures substantially. Tr. at 24:5803-04 (Addanki). The reasonable inference is that number of total potassium chloride prescriptions had little or no relationship to Schering's promotions.

3.356. This benefit of promotion is well understood in the economic literature. An article by Caves and others discusses how, because of the incentive structure created by laws that require mandatory substitution from brands to the AB-rated generics, the pioneer firms' incentives to promote dwindle, sometimes very sharply, in the wake of generic entry, producing two potentially offsetting effects. (24 Tr. 5809 (Addanki)). First, on the procompetitive side, the entry makes a drug available at lower prices than prevailed during the period of patent protection. Second, on the anticompetitive side, "even more importantly, it does not lead to increases in the quantities of the contested drug that are sold. Indeed, quantities may decrease relative to those

sold before patent expiration." (25 Tr. 6169 (Addanki)). To determine the net effect of generic entry, one must analyze each case on a case-by-case basis. (24 Tr. 5810 (Addanki)).

Complaint Counsel's Response to Finding No. 3.356:

The finding is contradicted by more reliable evidence and incomplete. The cited article identifies informational advertising, not all advertising, as a benefit. CPRF 3.351. The Caves article only raised the question of whether entry and subsequent loss of promotion could harm consumers. Tr. at 34:8063 (Bresnahan). This question has since been settled by subsequent articles, and economists have concluded that generic pharmaceutical entry benefits consumers. Tr. at 34:8059-60 (Bresnahan). *See* CPRF 3.345.

The opinion of Dr. Addanki that the consumer welfare effects must be measured in each case is unreliable. Dr. Addanki discussed only one article despite the fact that there have been four or five articles on the impact of generic entry in the pharmaceutical industry. Tr. at 3:494-95 (Bresnahan). They consistently find that generic entry lowers prices for consumers. Tr. at 3:495 (Bresnahan). In particular, an article by Iain Cockburn and Zvi Griliches resolved the issue of the benefits of generic entry in the pharmaceutical industry. Tr. at 34:8059-60 (Bresnahan). Dr. Addanki did not recall whether he had read the Congressional Budget Office study *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*. Tr. at 25:6110-11 (Addanki).

3.357. A study by Ernst Berndt and others that was published in Dr. Bresnahan's book,

"The Economics of New Goods," states that "at the industry level, both cumulative minutes of detailing and cumulative pages of medical journal advertising affect sales." (25 Tr. 6205 (Addanki)). The chapter indicates that "marketing efforts play a very important role in the diffusion of information to physicians . . . ." (USX 1090); (25 Tr. 6206 (Addanki)). Most importantly, the authors conclude that marketing efforts of pharmaceutical firms have substantial effects on "the size of the overall industry." (USX 1009); (5 Tr. 884 (Bresnahan); 25 Tr. 6207 (Addanki) (USX 1090).

Complaint Counsel's Response to Finding No. 3.357:

The document USX 1009 is not in evidence. Moreover, the finding is irrelevant to determining the impact of the specific agreements at issue in this case. Respondents have produced no evidence that consumers will be harmed by loss of promotion or that the size of the overall industry fell as a result of the entry of generic 20 mEq tablets. *See* CPRF 3.344.

The finding is irrelevant to the impact of generic entry in general or in the case at hand. None of the quoted material discusses the social welfare implications of reduced advertising in the context of generic entry.

USX 1090 has no relevance to this finding. USX 1090 has what appears to be notes of a meeting or phone call with Clinical Research Inc.

3.358. Indeed, even Professor Bresnahan conceded that this expansion of total quantity does not always happen in the pharmaceutical industry (6 Tr. 1196 (Bresnahan). And, Schering did not forecast an increase in total unit sales as a result of generic entry. (6 Tr. 1238-39

(Bresnahan), CX133). In fact, marketing and promotion activity might have a tendency to increase Schering's sales of an entire category of drugs, brand awareness on the part of doctors and patients, and the output of a particular drug. (4 Tr. 651 (Bresnahan)).

Complaint Counsel's Response to Finding No. 3.358:

The findings is incomplete and misleading. CX 133, the document read to Professor Bresnahan, forecasts four months of sales after generic entry. In other forecasts, both Schering and Upsher projected that K-Dur 20 and its generic would increase in total units after generic entry. SPX 1010 at SP 250024 ("Table: Capsule Scenario re K-Dur"); CX 770 at USL08543 ("Company Report").

The fact that advertising might have the proposed effects does not change the fact that generic entry benefits consumers and that there is no evidence that consumers were harmed by the entry of a generic K-Dur 20 product. *See* CPRF 3.344.

3.359. Thus, generic entry is not necessarily positive in terms of consumer welfare. (25 Tr. 5951-52)). The effects are ambiguous. (25 Tr. 6169 (Addanki)). There are both good and bad results from generic entry. (25 Tr. 5950-51 (Addanki)).

Complaint Counsel's Response to Finding No. 3.359:

The finding is contradicted by the evidence. Economists generally view entry by a competitor to be pro-consumer. The view is a primary reason that economists favor a competitive economy. The proponent of a contrary view would have the "hefty" burden of convincing a professional economist that competitive entry may harm consumers.

Respondents have produced no evidence that consumers will be harmed as a result of the entry of generic pharmaceuticals. *See* CPRF 3.344.

Dr. Addanki's opinion contradicts the established understanding of competition in general and of generic entry in the pharmaceutical industry. CPRF 3.344. His opinion is unreliable because he has reviewed and study little of the literature, CPRF 3.356. He provided opinions on the substance of Schering's Advertisements without reviewing those ads. CPRF 3.351. He provided an opinion on the relative frequency of informational and persuasive advertising without explaining how he made this determination and without discussing the persuasive advertising in the documents he relied on. CPRF 3.351. He opined on the competitive implications of a merger transaction that he had not studied. CPRF 3.350.

This finding is also irrelevant because, at the time of the settlement, there was no generic K-Dur 10 product available. Upsher's speculations on the impact of a generic K-Dur 10 product in the absence of a generic K-Dur 20 do not alter the facts that 1) Schering was able to raise the price of K-Dur 20 without losing sales (CPF 972-987); 2) generic K-Dur 20 was forecasted, and did take, substantial sales from K-Dur 20 at a substantial discount (CPF 952-971, 988-992); 3) only generic K-Dur 20 was forecasted, and did, force Schering to lower the price of its 20 mEq potassium supplement by launching its own generic K-Dur 20 (CPF 993-1036).

3.360. Despite his awareness that Schering had been working with doctors and other payers to enhance brand awareness of K-Dur 20, Professor Bresnahan did not undertake any

formal examination of the impact that Schering's marketing on the total market demand for potassium chloride products. (4 Tr. 651-52 (Bresnahan)). Consequently, Professor Bresnahan did not undertake the proper analysis and Complaint Counsel did not establish that a delay in entry is always anticompetitive on net.

Complaint Counsel's Response to Finding No. 3.360:

The finding is contradicted by the evidence. Economists generally view entry by a competitor to be pro-consumer. The view is a primary reason that economists favor a competitive economy. The proponent of a contrary view would have the "hefty" burden of convincing a professional economist that competitive entry may harm consumers. Respondents have produced no evidence that consumers will be harmed by loss of promotion or that the size of the overall industry fell as a result of the entry of generic 20 mEq tablets. Therefore, the analysis proposed in the finding is unnecessary and contrary to well-established theory and empirical research. CPRF 3.344.

III. SOCIAL BENEFITS OF SETTLEMENTS

A. Conservation of Resources

3.361. Settlements are generally procompetitive. (24 Tr. 5817 (Addanki)). Litigation consumes huge amounts of private resources, in terms of the cost of retaining lawyers and experts and diverting business people from running their businesses. (24 Tr. 5818 (Addanki)). A societal benefit of settlement is that it allows the parties to conserve resources and avoid transaction costs. (12 Tr. 2675 (Mnookin)). Settlement can mitigate uncertainty and allow the parties to avoid the risks of litigation, creating economic efficiencies. (12 Tr. 2675 (Mnookin)).

These transaction costs may include not only legal fees, but also the time and distraction of the parties and their personnel. (12 Tr. 2675 (Mnookin)).

Complaint Counsel's Response to Findings Nos. 3.361-63:

All these proposed findings are irrelevant because the Complaint does not challenge the settlement agreements, standing alone, but rather, Schering's making a cash payment to Upsher to induce it to agree to delay launching its generic product for a longer period than it would have agreed to in the absence of that payment. *See* Complaint ¶ 64. Schering has made no showing that the payment was necessary to reach settlement and thus to achieve the resource savings attendant on the settlement. Rather, the unchallenged evidence in the record shows that reverse payments of the type found in this case are not known by respondents' expert witnesses to have been used in the settlement of any other patent litigation, and that such payments are not necessary to settle patent lawsuits. CPF 1415-1420, 1425. In fact, respondents 'experts testified that cash payments are not an effective tool for value creation in settlements. CPF 1421-1424.

The proposed findings are incomplete because they do not recognize that settlement agreements can be anticompetitive and harmful to the public. Expert witnesses called by both respondents testified that settlement agreements can be anticompetitive. Tr. at 24:5860 (Addanki); Tr. at 29:7243 (Willig). Professor Mnookin admitted that a transaction that could be termed a value creating trade as far as the parties were concerned could come at the expense of third parties. If the arrangement involved the cooperation of the parties to create or exploit a monopoly, it would not be socially beneficial even if it was profitable for the companies involved. Tr. at 12:2684

(Mnookin).

The proposed findings are incomplete and misleading because they do not take into account the resource savings that consumers experience after a generic drug becomes available to them. CX 133, an Operating Plan prepared by Key Pharmaceuticals, estimated that for 1997, a generic priced at 50% of the K-Dur price would capture 50% of K-Dur volume. Based on these assumptions, consumer savings for the month of December, 1997, alone were projected to be $4.18 million. CX 133; Tr. at 6:1235-41 (Bresnahan). Data in the record permits us to make a rough estimate of the consumer savings that resulted from entry of Upsher's generic product into the market in 2001. By November of that year, generic products had captured 61% of the total number of prescriptions for 20 mEq potassium chloride tablets. CPF 989. K-Dur's net sales in 2000 amounted to $287,151,000. CX 695 at SP 020701. In 1997 and 1998, K-Dur 20 accounted for 91.8% of total K-Dur dollar sales. CX 687. Assuming annual sales of $287,151,000 (91.8% of which derives from sales of K-Dur 20), and using the actual prices and prescription percentages of generic products in November 2001, estimated annual consumer savings from the introduction of generic 20 mEq potassium chloride tablets were approximately $160.8 million.

3.362. Settlements also serve the public interest by promoting the conservative of judicial and administrative resources. The judicial system relies on settlements to avoid gridlock created by the hundreds of thousands of cases filed in court in the United States every year. (29 Tr. 7107 (O'Shaughnessy; 29 Tr. 7148-49 (Willig); 24 Tr. 5818 (Addanki)).

Complaint Counsel's Response to Finding No. 3.362:

Complaint Counsel has no specific response, *see* CPRF 3.361.

3.363. There are substantial social costs associated with patent litigations. (29 Tr. 7107-08 (O'Shaughnessy)). For every dollar spent on research and development, about 27 cents is spent on patent litigation. (29 Tr. 7107-08 (O'Shaughnessy)). If parties are not able to settle, the average cost of litigation increases, and less money is available for innovation. (29 Tr. 7108 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.363:

Complaint Counsel has no specific response, *see* CPRF 3.361.

B. Elimination of Risk

3.364. Intellectual property litigation, more so than other types of litigation, creates uncertainty in business planning. (29 Tr. 7065 (O'Shaughnessy)). For example, in the 1990's, the Federal Circuit's reversal rate in patent litigation appeals was about 50 percent. (29 Tr. 7065-66 (O'Shaughnessy)). Therefore, even businesses equipped to understand and predict the outcome of litigation are subjected to a certain degree of uncertainty. (29 Tr. 7066 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.364:

The proposed finding is irrelevant. First, there is no evidence that Schering was risk averse in the settlement of the patent infringement litigation with AHP and Upsher-Smith. (*See* Tr. at 4:609 (Bresnahan) (no evidence that Schering is risk averse), CPF

1266 - 1277 (the general understanding in economics that firms are risk neutral).). If Schering is not risk averse, then the degree of uncertainty around any particular litigation is irrelevant. *See* SPF 3.239 (definition of risk aversion). Second, nowhere in the cited testimony did Mr. O'Shaughnessy opine that uncertainty in the K-Dur patent infringement litigation created business planning uncertainty for any of the respondents, nor even that uncertainty in patent infringement litigation creates business planning uncertainty for pharmaceutical companies in general. Tr. at 29: 7065-7067 (O'Shaughnessy). Indeed, Mr. O'Shaughnessy admitted that his only experience with patent cases involving pharmaceuticals was over twenty years ago and involved Sensodyne Toothpaste. Tr. at 29:7109 (O'Shaughnessy). He further conceded that he has no expertise in either Hatch Waxman patent infringement cases or the pharmaceutical industry. Tr. at 29:7109 (O'Shaughnessy).

3.365. In the business planning process, such extraordinary uncertainty confounds the decision-making process and makes resource allocation much more difficult. (29 Tr. 7066 (O'Shaughnessy)). Accordingly, business managers generally "deplore" patent litigation, as it hinders their ability to allocate scarce resources and make a plan for the company that will endure. (29 Tr. 7066 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.365:

The proposed finding is irrelevant. *See* CPRF 3.364.

3.366. Litigation-related uncertainty also affects investments, because investments can be

made more rationally and reasonably under conditions of certainty. (29 Tr. 7067 (O'Shaughnessy)). Only with a greater degree of predictability can one make a plan to invest in the development of a new product and to engage in the investments necessary to bring it to market. (29 Tr. 7067 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.366:

The proposed finding is irrelevant. *See* CPRF 3.364.

3.367. Settlement can mitigate uncertainty and allow the parties to avoid the risks of litigation, thus creating economic efficiencies. (12 Tr. 2675 (Mnookin)). By resolving the uncertainty, the firm can return to planning for the future without having the uncertainty hanging over its head. (24 Tr. 5769 (Addanki)). It is easier for a firm to develop investment strategies without the threat of litigation. (24 Tr. 5769 (Addanki)).

Complaint Counsel's Response to Finding No. 3.367:

The proposed finding is irrelevant in part and contradicted by other evidence in part. It is irrelevant because there is no evidence that Schering was risk averse (*See* Tr. at 4:609 (Bresnahan) (no evidence that Schering is risk averse), CPF 1266 - 1277 (the general understanding in economics that firms are risk neutral).). It is contradicted by other evidence, because it ignores the evidence that diversifiable risks are not important to corporations or shareholders. *See* CPRF 3.246.

3.368. A settlement of a patent dispute removes the burden of risk to the parties that is present if the litigation goes forward. (29 Tr. 7148 (Willig)). The presence a risk may result in

less investment, because the aversion to risk causes the firm to avoid investments that it might otherwise make. (29 Tr. 7169-70 (Willig)). In the corporate environment, the most direct interaction between risk aversion and less investment is the cost of capital to the corporation. (29 Tr. 7170 (Willig)). The riskier the corporate holdings, the higher the cost of capital, and a higher cost of capital makes investment less desirable. (29 Tr. 7170 (Willig)). If the outcomes of a portion of the company's business are uncertain, then there is an extra reason for the company to delay investment until some of the uncertainty clears. (29 Tr. 7170 (Willig)). The company that does not wait until the uncertainty clears will make mistakes because of the inability to foresee the future. (29 Tr. 7170 (Willig)). The riskier the future, the more likely a misjudgment is and the wrong investment is made as a result of that risk. (29 Tr. 7170 (Willig)). A prohibition on settlements would result in businesses bearing undue risk and the costs of those risks. (29 Tr. 7235 (Willig).

Complaint Counsel's Response to Finding No. 3.368:

The proposed finding is irrelevant in part and contradicted by other evidence in part. *See* CPRF 3.367 and 3.246.

C. Settlements with Side Deals Create Value

3.369. Professor Mnookin is the Chairman of the Program on Negotiation at Harvard Law School. (12 Tr. 2666 (Mnookin). He is also the director of the Harvard Negotiation Project. (*Id.*) He regularly teaches courses in negotiation and dispute resolution. (12 Tr. 2667 (Mnookin).

Complaint Counsel's Response to Finding No. 3.369:

Complaint counsel has no specific response.

3.370. Professor Mnookin emphasizes the importance of searching for value-creating trades that are unrelated to the subject of the dispute in his teaching, as well as in his writing. (12 Tr. 2679-80 (Mnookin)). It is a central theme of his book, *Beyond Winning*. (12 Tr. 2680 (Mnookin)). Other leaders in the dispute resolution field, including Professor Steve Goldberg, Professor Frank Sander, and Professor Roger Fisher, agree on the importance of this settlement mechanism. (12 Tr. 2680 (Mnookin)). Professor Mnookin teaches his students to look for such value creating trades, and he personally uses this technique when serving as a mediator or a neutral. (12 Tr. 2681 (Mnookin)). Professor Mnookin teaches his students to look for things that are relatively cheap for one side to give up that may be valued more highly by the other side. (12 Tr. 2679 (Mnookin). Professor Mnookin uses the following example: "you're looking for opportunities for a carnivore to trade broccoli to a vegetarian who has some lamb chops." (*Id.*). If parties can create value through an unrelated transaction, that value will also make it possible for them to each be better off with the side transaction than continuing to litigate. (12 Tr. 2678 (Mnookin)).

Complaint Counsel's Response to Findings No. 3.370:

The proposed finding is incomplete. Professor Mnookin admitted that a transaction that could be termed a value creating trade as far as the parties were concerned could come at the expense of third parties. If the arrangement involved the cooperation of the parties to create or exploit a monopoly, it would not be socially

beneficial even if it was profitable for the companies. Tr. at 12:2684 (Mnookin). In addition, Professor Bazerman testified that settlement agreements involving creation of extrinsic value for the parties are not beneficial if the value used to facilitate the settlement has been taken from third parties. Tr. 36:8493-98; 8500-01 (Bazerman); CPF 1410. Value creation in settlements that comes at the expense of consumers harms society. Tr. 36:8501 (Bazerman); CPF 1412.

Professor. Mnookin also testified that he was not aware of any case (other than this one) involving an infringement claim brought only by the plaintiff (as opposed to cross claims based on intellectual property held by each party) where the patent holder paid the accused infringer to settle). Tr. at 12:2691-92.

3.371. Mediators use this technique to facilitate settlements. The mediator persuades the parties to work collaboratively to develop some extrinsic value to bridge that gap. (29 Tr. 7081-82 (O'Shaughnessy)). The new opportunity could be a new relationship such as customer-supplier, licensor-licensee, or an alliance. (29 Tr. 7082 (O'Shaughnessy)). When the parties succeed at developing an extrinsic value, they can import it back into the dispute and find a way to bridge the gap in their positions, arriving at a global settlement of the dispute. (29 Tr. 7082 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.371:

The proposed finding in incomplete. Mr. O'Shaughnessy also testified that cash payments such as those found in this case are not an effective tool for value creation in settlements. CPF 1421-1424.

3.372. Often parties arrive at patent-splitting arrangements, where the parties split the rights of the patent, such as the territorial rights, fields of use, and performance rights. (29 Tr. 7090-91 (O'Shaughnessy)). Mr. O'Shaughnessy has been involved in matters where consideration has flowed in both directions. (29 Tr. 7132 (O'Shaughnessy)). In those deals, both cash and rights were exchanged between the parties. (29 Tr. 7132 (O'Shaughnessy)). The cash could be paid in return for a license. (29 Tr. 7132 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.372:

The proposed finding is incomplete. Mr. O'Shaughnessy also testified that he had not been involved in any patent case settlement in which the patent holder paid the alleged infringer a cash payment up front at the time of settlement. Tr. at 29:7109 (O'Shaughnessy); CPF 1417.

3.373. Dr. Addanki has also been involved with numerous cases where there was a settlement concerning patents outside the scope of the litigation, and frequently those cases involved consideration in one form or another. (24 Tr. 5911 (Addanki)). Indeed, patent infringement settlements virtually all have multidimensional side deal aspects, with unrelated intellectual property rights moving in both directions between parties. (27 Tr. 6350-51 (Kerr) (25 Tr. 6801 (Addanki)).

Complaint Counsel's Response to Finding No. 3.373:

The proposed finding is incomplete. Dr. Addanki also testified that he was not aware of any pharmaceutical patent case settlements (other than those challenged in this proceeding) where there was a naked cash "reverse payment". Tr. at 24:5910, 5912

(Addanki); CPF 1417. Dr. Addanki also testified that most patent cases do settle, and they do so without one-way payments by the patentee to the alleged infringer. Tr. at 25:6081 (Addanki); CPF 1419.

3.374. Extrinsic value creation has been essential to the settlement of at least half the cases in which Mr. O'Shaughnessy has been involved. (29 Tr. 7082-83 (O'Shaughnessy)). If extrinsic value creation is taken out of the repertoire of the mediator by a rule of law, half of the settlement that Mr. O'Shaughnessy achieved would have not have happened at all. (29 Tr. 7083 (O'Shaughnessy)). Removing this method from settlement negotiation would have a "profound and negative impact" on mediation. (29 Tr. 7083 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.374:

The proposed finding is irrelevant. Complaint counsel are not seeking in this case to establish a rule of law that takes "extrinsic value creation" "out of the repertoire of the mediator" seeking to facilitate settlement of litigation. Rather, the rule of law being sought would prohibit "payment to a potential competitor to secure an agreement not to enter [the market] and compete." Complaint Counsel's Brief in Support of Proposed Findings of Fact and Conclusions of Law 47 (April 15, 2002).

3.375. Intellectual property licenses are an example of a value-creating trade. The company that initially develops the product is not necessarily the one that is best suited to take it through the regulatory process and bring it to market. (27 Tr. 6357 (Kerr)). For example, Upsher would not have been able to market Niacor-SR outside the U.S. (27 Tr. 6357 (Kerr)).

Complaint Counsel's Response to Finding No. 3.375:

The proposed finding is irreverent. The licenses for the intellectual property in this case were not a value creating trade. Schering paid Upsher $60 million not for licenses, but for delay. Three categories of evidence prove that, in fact, Schering paid Upsher $60 million to delay Upsher's entry into the K-Dur 20 market: (1) the circumstances of the negotiations and the Schering/Upsher Agreement itself; (2) an analysis of the license for Niacor-SR; and (3) the economic incentives of branded monopolies and potential generic entrants:

(1) First, the text of the Schering/Upsher Agreement and the circumstances of the negotiations indicates payment for delay. The Schering/Upsher Agreement itself indicates that the license and supply agreement was not a separate agreement for value independent of the settlement agreement, but in fact that the $60 million and the agreement to settle the patent infringement suit were inextricably intertwined. CPF 176 (paragraph 11 of the Schering/Upsher Agreement explicitly states $60 million is for paragraphs 1-10 of the Schering/Upsher Agreement, which includes the settlement of the litigation, Upsher's agreement to delay entry until 2001, and its agreement not to help any other challengers to the '743 patent); CPF 178 (Mr. Hoffman concedes that the agreement on its face indicates some money paid for settlement); CPF 179 (paragraph 3 allows Upsher to come to market immediately if a court strikes down the Agreement (and thus Schering's requirement to pay the $60 million)); CPF 181 (paragraph 3 allows Upsher to come to market if Schering licenses another generic to enter); CPF 180 (paragraph 10 ("*force majeure*" clause) obligates Schering to pay $60 million to Upsher even if some

unforeseen event causes the license to be worthless). This contemporaneous documentary evidence is more reliable than the self-serving, post-hoc testimony cited in the proposed finding.

There is also reliable evidence that Mr. Troup asked for money from Schering repeatedly in order to agree to settle the Schering/Upsher patent infringement suit. CPF 190, 200, 204 (Mr. Troup demands for $60-70 million to settle the lawsuit at the May 21 meeting); CPF 191, 206, 209 (Mr. Troup stresses his need for cash at the May 28 and June 3 meetings); CPF 192, 194, 200, 206 (Mr. Troup repeats his demand for money to settle the lawsuit at the June 12 meeting); CPF 196, 200 (Mr. Troup stressed a need for an income stream and up-front payments as part of a settlement at the June 16 meeting); CPF 201 (Mr. Troup repeats his need for revenue as part of a settlement at the June 17 meeting).

Mr. Troup based these requested requests for money from Schering to settle the lawsuit not on the value of Niacor, but instead on Upsher's forgone revenues for not entering the market and the revenue impact its product would have on Schering's K-Dur 20 monopoly if Upsher entered the market. CPF 200-02 (discussing Mr. Troup repeatedly sought to replace revenues lost by not being on the market); CPF 204, 212-13 (discussing Mr. Troup requesting $60-70 million to end the litigation and basing that figure on a percentage of the harm that Upsher's product would do to Schering's monopoly); CPF 206-07 (discussing Mr. Kapur and Mr. Wasserstein's testimony that Mr. Troup wanted to replace the revenue Upsher was losing by delaying entry); CPF 214-18 (discussing money requested to settle the lawsuit based on Upsher's lost revenues from

not entering the generic K-Dur 20 market).

(2) Second, the $60 million non-contingent payment made by Schering to Upsher cannot reasonably be considered to have been a license fee for Niacor-SR and the five generic products licensed under the settlement agreement. Tr. at 7:1307, 1338-39 (Levy); Tr. at 4:577 (Bresnahan). The $60 million non-contingent fee was grossly excessive for Niacor-SR and the other licensed products, CPF 287-372, Schering's due diligence was strikingly superficial relative to industry standards, CPF 373-663, Schering's and Upsher's post-license behavior does not comport with parties' who had just entered into a typical licensing deal, CPF 664-721, Schering had previously rejected an equal or better product, CPF 722-777, and no other company had offered Upsher any money for Niacor-SR, let alone $60 million, CPF 778-808.

(3) Third, economic theory proves Schering paid Upsher $60 million to delay Upsher's entry into the K-Dur 20 market. There is always an incentive for the monopolist to pay the entrant to delay its entry and for the entrant to agree to delay its entry, which harms consumers. CPF 1150-1160. A monopolist and potential entrants have those incentives to delay entry even with it is uncertain. CPF 1161-1165. Uncertain competition provides the same benefits qualitatively as certain entry, so delaying uncertain entry harms consumers. CPF 1166-1172. Applying the criteria to these settlements, Schering was a monopolist and Upsher and AHP were threats to that monopoly. Therefore, the parties had the incentives to delay uncertain entry. CPF 1173-1184 (applying economic theory to facts of this case and explaining how Schering, as a monopolist, had the incentive to pay Upsher to delay its entry and how Upsher, as a

potential entrant, had the incentive to accept money to delay its entry). Schering paid Upsher net consideration for delay. CPF 1185-1208 (explaining Schering's and Upsher's incentives to agreement to payment for delay, the actions of each which led to payment for delay, and that the $60 million was not for Niacor-SR).

Additionally, that $60 million Schering paid to Upsher encompassed some of Schering's K-Dur monopoly profits. These monopoly profits came at the expense of consumers. CPF §XII. This is the type of trade referred to as "parasitic integration," in which the extrinsic value used to consummate the deal came at the expensive of a third party; in this case, consumers. It was thus not of a type of settlement that is considered socially beneficial. CPF 1409-12.

D. The Chilling Effect of a Rule Limiting Side Deals On Settlements

1. Patent Splitting Arrangements With or Without Linked Fair Value Extrinsic Transactions

3.376. Both Complaint Counsel and Respondent's economists agree that there should be no concern about a settlement that splits the patent life or splits the patent life with a side deal without net consideration flowing to the generic. (5 Tr. 932-933, 937-38 (Bresnahan); 29 Tr. 7147-51 (Willig)). Such settlements create little risk of impeding competition, because it is not likely to create more monopoly than would litigating. (29 Tr. 7151 (Willig)).

Complaint Counsel's Response to Findings No. 3.376-86:

All these proposed findings are irrelevant because the complaint does not

challenge settlement agreements with "side deals," standing alone, but rather, Schering's making a cash payment to Upsher to induce it to agree to delay launching its generic product for a longer period than it would have agreed to in the absence of that payment. *See* Complaint ¶ 64. One of the prongs of the test that Professor Bresnahan employed in his analysis of whether a settlement agreement was anticompetitive was whether there was a payment to delay generic entry into competition with a monopoly product. Tr. at 3:41 (Bresnahan). This question is relevant because if the payment is for delay, then the potential threat to the monopoly power is reduced or delayed into the future. Such a delay or reduction in the threat to monopoly power is anticompetitive. Tr. at 3:421-22 (Bresnahan). By its own terms, therefore, the analysis that Professor Bresnahan employed applies only to certain kinds of "side deals" and only in a very limited subset of all patent litigation settlements.

The proposed finding is contradicted by other evidence in the record. Schering's settlement expert, Mr. O'Shaughnessy, admitted that a rule prohibiting net consideration flowing from the patentee to the entrant would affect only a small number of settlement, relative to the number of lawsuits. Tr. at 29:7111-13. Moreover, Schering has made no showing that payment of the type challenged in this case are necessary to reach settlements. Rather, the unchallenged evidence in the record shows that reverse payments of the type found in this case are not known by respondents' expert witnesses to have been used in the settlement of any other patent litigation, and that such payments are not necessary to settle patent lawsuits. CPF 1415-1420, 1424. In fact, Schering's patent settlement expert testified that cash payments are not an effective tool for value creation

in settlements. CPF 1421-1424. Thus, there is no basis for the conclusion that the rule of law complaint counsel seeks would have a "chilling effect" on side deals in settlements.

3.377. Even if the patent splitting arrangement is accompanied by a fair-value side deal, it raises no significant issues of competitive concern and should not be the subject of intervention. (29 Tr. 7147 (Willig)). Like settlements without side deals, they raise no additional risks of harm to competition or the creation of more monopoly. (29 Tr. 7153-54 (Willig)). There is also the extra benefit that the side deal may help facilitate the attainment of a settlement in the first place, which has its own social benefit. (29 Tr. 7154 (Willig)). Thus, Professor Willig agrees with complaint counsel's decision not to challenge the settlement of patent disputes by an agreement on a date of entry, standing alone, or by the payment of fair market value in connection with side deals to such an agreement. (29 Tr. 7154 (Willig)).

Complaint Counsel's Response to Finding No. 3.377:

Complaint Counsel has no specific response, *see* CPRF 3.376.

2. The Link Between the Extrinsic Value Creation Components and the Settlement

3.378. Professor Bresnahan testified that under his rule, litigants could not facilitate the settlement of a patent litigation through a linked extrinsic deal. Professor Bresnahan testified, "If you wanted to be safe, the thing to do would be break the linkage." Breaking the linkage means that the branded firm has to be able to walk away from the licenses and the generic has to be able to walk away from the settlement. Professor Bresnahan could not think of a single integrated

transaction that would satisfy the Bresnahan rule. (5 Tr. 1019-20 (Bresnahan).

Complaint Counsel's Response to Finding No. 3,378:

The proposed finding is misleading. Professor Bresnahan did not testify that litigants could not facilitate the settlement of a patent litigation through a linked extrinsic deal; that breaking the linkage between the settlement and the extrinsic deal was the only to avoid a conclusion that there was no transfer of net value to the potential entrant; that the parties being able to walk away from parts of the deal was the only way to break the linkage between the two deals; or that there was no "single integrated transaction that would satisfy the Bresnahan rule."

At the cited part of the transcript, Professor Bresnahan was asked : "What does Schering-Plough have to do to calculate net positive value so that it's safe in doing the side licensing deal? *Can you just give me an example?*" Tr. at 5:1019 (emphasis added). In his answer, Professor Bresnahan gave one such example: "Oh, there's an easy way. Just split the deals . . . " Tr. at 5:1019 (Bresnahan).

A bit later, Professor Bresnahan was asked whether his positions was that "Schering-Plough needs to do some kind of ordinary course of business assessment of the licensing in order to be safe with the valuation calculation, sir?" His answer was: "In order to be safe? . . . If you wanted to be safe, the thing to do would be to break the linkage." Tr. at 5:1021 (Bresnahan).

In between these two exchanges, Professor Bresnahan testified that he would not say that two deals were linked if the branded firm can walk away from the licenses and the generic entrant can walk away from the patent settlement. Tr. at 5:1019-20

(Bresnahan). His statement that there could not be a single, global transaction that would have "readily satisfied the Bresnahan test" (Mr. Gidley's words) was in response to a question relating specifically to the Schering/Upsher agreement at issue in this case. *See* CPRF 3.376.

3.379. Mr. O'Shaughnessy understands Professor Bresnahan's approach to require two delinked transactions. (29 Tr. 7098 (O'Shaughnessy)). Mr. O'Shaughnessy says that this approach would make most settlements difficult or impossible to achieve. (29 Tr. 7099 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.379:

The first sentence is contrary to more reliable evidence. Mr. O'Shaughnessy has misinterpreted Professor Bresnahan's approach; therefore, Mr. O'Shaughnessy criticisms of Professor Bresnahan are irrelevant. CPRF 3.378.

The second sentence of the proposed finding is contradicted by other evidence in the record. Professor Bazerman, an expert in the fields of negotiation and dispute resolution, Tr. at 36:8488 and 8491, disagreed with the opinion that to the extent that net consideration was not allowed in settlement agreements, parties would be less likely to settle litigation. In stead, he testified that such a rule could properly chill agreement where the parties were creating value for themselves at the expense of consumers, but that he saw no reason "why parties wouldn't continue to be able to reach those kinds of agreements" that "create true joint value without taking it from the consumers." He concluded that "the only agreement that I see being chilled are agreements that society

would be better off having chilled.." Tr. at 36:8523 (Bazerman).

3.380. The value-creating deal is linked to the ability to achieve settlement. After developing an extrinsic value-creating deal, parties do not continue litigating the case. (29 Tr. 7086-87 (O'Shaughnessy)). To do so would be illogical, because the transaction and the settlement are simply multiple components of the same transaction. (29 Tr. 7087 (O'Shaughnessy)). Further, the parties are attempting to work together in the value-creating deal, and a continuing "rancorous dispute" would not foster such cooperation. (29 Tr. 7087-88 (O'Shaughnessy)). Finally, if there were a payment involved in the extrinsic deal, the party would effectively be funding the other party's litigation. (29 Tr. 7088 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.380:

This meaning of this proposed finding is unclear. It appears to suggest that Mr. O'Shaughnessy believed that "delinking" the transactions would require the parties to continue the litigation after they entered into to side deal. This conclusion does not follow either from Professor Bresnahan's testimony itself, discussed at Proposed Finding 3.378, or from Mr. O'Shaughnessy's testimony that his understanding of the delinking concept was that "if it's a worthy transaction in the scope of settling the dispute, it's equally worthy outside the scope of the dispute." Tr. at 29:7098.

To the degree that this proposed finding suggests that banning net consideration being paid by monopolists to generic entrants to delay entry, the finding is contrary to more reliable evidence. *See* CPRF 3.381.

3.381. Professor Willig testified that any requirement to sever settlements and side deals would have a negative impact on social welfare (29 Tr. 7155-57 (Willig)). If parties trying to reach a settlement found it dangerous to link a side deal, whether or not it involved net consideration, it would be harder for to settle of the underlying litigation (29 Tr. 7157 (Willig)). Such rule also contrary to conserving judicial resources (29 Tr. 7157-58 (Willig)).

Complaint Counsel's Response to Finding No. 3.381:

The proposed finding is contradicted by other evidence in the record. Professor Bazerman, an expert in the fields of negotiation and dispute resolution, Tr. at 36:8488 and 8491, disagreed with the opinion that to the extent that net consideration was not allowed in settlement agreements, parties would be less likely to settle litigation. Instead, he testified that such a rule could properly chill agreement where the parties were creating value for themselves at the expense of consumers, but that he saw no reason "why parties wouldn't continue to be able to reach those kinds of agreements" that "create true joint value without taking it from the consumers." He concluded that "the only agreement that I see being chilled are agreements that society would be better of having chilled.." Tr. at 36:8523 (Bazerman).

Moreover, the proposed finding is contradicted by the testimony of Dr. Willig himself and other of respondent's expert witnesses. Dr. Willig admitted that he knew of no real-world instance in which parties were not able to settle because there a was a gap in the parties' positions and no one was able to pay net consideration to the other to help bridge the gap. Tr. at 29:7316 (Willig); CPF 1418. Professor Mnookin, Dr. Addanki, Mr. Miller and Mr. O'Shaughnessy all admitted that the were not familiar with any patent

settlements, other than the ones involved in this case, where the patent holder make a one-way cash payment to the alleged infringer in a settlement agreement. CPF 1417. Yet, Dr. Addanki, Dr. Willig, and Dr. Kerr all acknowledged that a majority of patent cases do settle. CPF 1419. No witness in this proceeding provided testified to any knowledge of cash payments of the type found here having occurred in the settlement of any other patent case.

3. The Level of Due Diligence Performed on Value-Creating Trades Linked to Settlements

3.382. Professor Bresnahan's analysis would require a firm to engage in customary due diligence in the extrinsic value creation transaction. This would make most settlements difficult or impossible to achieve. (29 Tr. 7098-99 (O'Shaughnessy)) With pressure to settle, there is no time to perform customary due diligence. (29 Tr. 7099 (O'Shaughnessy)). The parties will only become more polarized with the passage of time. (29 Tr. 7099 (O'Shaughnessy)).

Complaint Counsel's Response to Findings No. 3.382-86:

The proposed findings are misleading in the suggestion that the absence of due diligence on value-creating trades linked to settlements would lead to the conclusion that net consideration had been paid or that the agreement was anticompetitive. As was discussed in connection with complaint counsel's response to proposed finding 3.378, Professor Bresnahan did not testify that the absence of "ordinary course of business assessment of the licensing" would necessarily result in a conclusion that a side deal was anticompetitive. The third prong of Professor Bresnahan's analysis was whether there

was a payment to delay generic entry into competition with a monopoly product. Tr. at 3:419 (Bresnahan). The presence of net consideration is only one part of the test, and the absence of due diligence is only one part of the analysis of whether net consideration was paid. In this matter, lack of normal due diligence is only one of 6 grounds (including evidence relating to the negotiation of the agreement) that we rely on to support the conclusion that the $60 million payment was not for the licenses. *See* CPF 166-808.

Complaint Counsel's Response to Findings No. 3.382:

The proposed finding is contrary to reliable evidence. Possessor Bresnahan never stated that parties must do ordinary due diligence. CPRF 3.378.

The proposed finding is contrary to Mr. O'Shaughnessy's own testimony. Although he testified that equal or pessimistic assessments of the patent case are not seldom at the end of litigation: "I mean by the end of the process, and you might take advantage and create some pessimism to drive a party to settlement." 29 Tr. at 7126-27 (O'Shaughnessy).

3.383. As a mediator, Mr. O'Shaughnessy tries to create a sense of pressure to settle while simultaneously bringing the parties together in a consensual process. (29 Tr. 7094-95 (O'Shaughnessy)). Once the settlement process gains momentum, a mediator "galvanize[s] that pressure." (29 Tr. 7095 (O'Shaughnessy)). A mediator tells the parties that this is their last chance to seize the offered opportunity, to "get it, strike while the iron is hot" that "[t]here is no time for a lot of analysis," and that there is no time for "endless due diligence." (29 Tr. 7096

(O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.383:

Complaint Counsel has no specific response, *see* CPRF 3.382.

3.384. If a rule were made that parties to multidimensional settlements were required to undertake customary due diligence, it would be much more difficult to enter into such settlement agreements. (26 Tr. 6356 (Kerr)). This would reduce the number of pro-competitive outcomes. (26 Tr. 6357 (Kerr)).

Complaint Counsel's Response to Finding No. 3.384:

Complaint Counsel has no specific response, *see* CPRF 3.382.

3.385. Even if an analyst had evaluated a potential extrinsic value-creating transaction and approved it, Mr. O'Shaughnessy could still not go forward with extrinsic value creation, if the company normally engages in extensive due diligence. (29 Tr. 7106-07 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.385:

Complaint Counsel has no specific response, *see* CPRF 3.382.

3.386. "It would be unsafe ... to proceed further with the settlement." (29 Tr. 7107 (O'Shaughnessy)). Accordingly, very few disputes would be settled if the FTC required proof that there was no net consideration. (29 Tr. 7133-34 (O'Shaughnessy)).

Complaint Counsel's Response to Finding No. 3.386

This finding, and Mr. O'Shaughnessy's testimony, lead to the conclusion that no

settlement, no matter how anticompetitive it is, should be subject to antitrust or any other review, because it would chill settlement agreements. This is an extraordinary assertion, not supported by any evidence except the unsupported opinions of respondents' experts, and inconsistent with common sense. Morever, it is inconsistent with the law. *See* Complaint Counsel's Brief in Support of Proposed Findings of Fact and Conclusions of Law 65-66 (April 15, 2002).

The proposed finding is contrary to more reliable evidence. *See* CPRF 3.381. *See* CPRF 3.382.

CERTIFICATE OF SERVICE

I, Pamela L. Timus, hereby certify that on May 14, 2002, I caused two copies of the "Public Version" of the following:

- Complaint Counsel's Reply to Schering-Plough's Proposed Findings of Fact Relating to the Settlement with ESI-Lederle
- Complaint Counsel's Reply to Schering-Plough's Proposed Findings Relating to the Underlying Patent Cases
- Complaint Counsel's Reply to Schering-Plough's Proposed Findings of Fact Relating to the Settlement with Upsher-Smith (Volumes 1 & 2)
- Complaint Counsel's Reply Brief
- Complaint Counsel's Reply to Schering-Plough's Proposed Economic and Policy Findings
- Complaint Counsel's Reply to Upsher-Smith's Proposed Findings of Facts (Volumes1 thru 3)

to be served by hand delivery upon:

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

and one copy upon the following persons via Federal Express:

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