UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

DOCKET NO. 9297

IN THE MATTER OF

SCHERING-PLOUGH CORPORATION,

UPSHER-SMITH LABORATORIES, INC.,

and

AMERICAN HOME PRODUCTS CORPORATION

APPEAL BRIEF OF COUNSEL SUPPORTING THE COMPLAINT

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The following abbreviations and citation forms are used:

ID - Initial Decision

IDF - Initial Decision Finding of Fact

CX - Complaint counsel exhibit

SPX - Schering-Plough exhibit

USX - Upsher-Smith exhibit

CPF - Complaint Counsel's Proposed Findings of Fact, filed April 15, 2002

SPF - Respondent Schering-Plough Corpc ' 's Corrected Proposed Findings of Fact Relating to the Settlement with Upsher Smith Laboratories, Inc., filed April 18, 2002

Schering Br. - Respondent Schering-Plough Corporation's Corrected Brief in Support of its Proposed Findings of Fact and Conclusions of Law Regarding the Upsher-Smith Settlement, filed April 18, 2002

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

Citations to the trial transcript include the volume, page number, and witness name: Tr. 12:2720-21 (Driscoll).

Pages of exhibits are referenced by bates number: CX 348 at USL03188.

References to investigational hearing or deposition transcripts that have been included in the trial record as exhibits include the exhibit number, the transcript page(s), the witness name, and the designation "IH" or "dep": CX 1492 at 85-86 (Dey IH).

In camera documents, testimony, and findings are designated by the notation [in camera] following the citation: CX 133 [in camera].

STATEMENT OF THE CASE

This case arises out of Schering-Plough's agreements with two companies seeking to market low-cost generic versions of K-Dur 20, Schering's widely-prescribed potassium supplement. By 1997, Schering was earning over $170 million annually selling K-Dur 20, a drug taken by millions of older Americans. Generic entry would decimate Schering's K-Dur 20 sales, and any delay in the introduction of a generic version would be highly profitable for Schering (but costly for consumers). When threatened with generic competition, Schering settled patent infringement suits brought against its prospective competitors, by paying them to forestall their market entry.

Schering paid $60 million to Upsher-Smith and $15 million to American Home Products, and these generic manufacturers agreed not to launch their products for several years. Each stayed out of the market as promised. As a result, the agreements eliminated competition, preserved Schering's K-Dur 20 profits, and harmed patients who need K-Dur 20 as therapy for chronic conditions.

It is undisputed that the written settlement agreements provide for large cash payments from Schering to Upsher and AHP; that the generics agreed to abandon their challenges to Schering's patent; that they agreed not to enter for several years; that Schering made the payments; and that the generics stayed out. In addition, Schering does not dispute that Upsher and AHP expressly asked for multi-million dollar payments to stay off the market. Respondents claim, however, that the payments Schering admittedly made were for something else.

As this brief discusses, and as the record demonstrates, Schering paid Upsher and AHP to stay off the market. The ALJ reached a different conclusion only by fully crediting self-serving testimony (such as testimony by Upsher's president that the plain terms of the agreement must be

a "typo") and anecdotal evidence belied by the parties' own data.[1] As the Commission will find on a full review of the record, the parties' contemporaneous business records, their conduct, and the terms of their agreements all point to one conclusion: respondents entered into agreements in which Schering paid the generics in exchange for their agreements not to launch their products for several years.

The remaining question for the Commission is whether these agreements are unlawful. Ordinarily, an agreement in which a potential competitor is paid to stay off the market is so plainly anticompetitive that it can be condemned out of hand. The ALJ concluded that a different outcome was warranted in this case, however, because these agreements arose in settlement of patent litigation. He began with the premise that Schering's patent entitled it to exclude generics from the market, and concluded there was no competitive harm unless we could show that Schering would have lost its patent cases (a showing that he acknowledged was impossible).

The ALJ's analysis is premised on a fundamental error. A patent does not give the patent holder the unfettered right to exclude competitors. Rather, it gives the patent holder the right *to seek a judicial determination* excluding its competitors. The patent holder must prove infringement, and the patent's validity is a rebuttable (not conclusive) presumption. The risk that the court will allow the competitor to enter the market royalty-free gives the competitor leverage to negotiate with the patent-holder for a settlement that reflects this risk. The patent rules

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[1] Where the ALJ's findings are based on such unreliable evidence and ignore much of complaint counsel's evidence, the Commission substitutes its own findings of fact and conclusions of law for those in the initial decision. *See, e.g., Adolph Coors Co.*, 83 F.T.C. 32, 177 (1973).

established by Congress, which create this *risk* that a patent will be found invalid or not infringed, thus benefit consumers regardless of what the trial's outcome actually would be.[2]

Schering's payments to Upsher and AHP amounted to "insurance" against this risk – insurance that Schering had no legal right to buy, and for which consumers paid a high price. That Schering purchased protection from possible rather than actual competition does not alleviate the fundamental antitrust concern with the challenged agreements.[3] Nor does it matter whether the parties would have been able to settle without arrogating this consumer benefit to themselves. Without a payment, the parties either would have settled anyway, or tried the case. Either way, as our economic expert, Professor Timothy Bresnahan, explained, the expected entry date is earlier than the date that rational parties would cho[illegible] a payment. Indeed, for each scenario respondents devised to explain how a settlement with payment from the patentee might result in earlier entry than expected from litigation (scenarios which generally required a complex combination of circumstances, none of which was shown to be present), Professor Bresnahan showed that it would have been economically irrational for the parties to pick anything other than a later entry date.

In short, the facts show that the parties expressly agreed to pay for less competition. Such an arrangement ordinarily would be *per se* illegal, and the parties have advanced no ground that would justify different treatment here. Whether the agreements are judged under a *per se*

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[2] For a discussion of these principles, *see* Keith Leffler & Christofer Leffler, *Want to Pay a Competitor to Exit the Market? Settle a Patent Infringement Case,* 2 ABA Econ. Committee Newsl. 26, 31-32 (2002).

[3] *See United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (per curium).

standard or receive closer examination under the rule of reason, however, the record establishes a violation. The Commission should reverse.

A. Facts

1. Schering's K-Dur 20

Schering sells a widely-prescribed potassium chloride supplement known as K-Dur 20, which is used by millions of Americans, particularly the elderly. Potassium chloride supplements are used to treat potassium deficiency, a condition that often arises among individuals who take diuretics to treat high blood pressure or congestive heart disease. Because these are chronic conditions, K-Dur 20 is generally a long-term therapy. CPF 940.

2. Market structure

K-Dur 20, while the most frequently prescribed, is one of many potassium supplements sold in the United States. Until generic entry in 2001, it was the only one available in a 20 milliequivalent[4] (mEq) tablet dosage. It has a unique micro-encapsulated extended-release mechanism that Schering promoted as providing superior protection against risk of ulcers. CPF 62. The other products available were 8 and 10 mEq tablets and capsules, along with various liquids, effervescent tablets, and powders. Tablets and capsules account for virtually all potassium supplement prescriptions.[5]

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[4] *See* Appendix B (glossary).

[5] *See* CX 81 (93.9% in 1994); CX 65 (96.5% in 2000).

During 1996, new generic 8 and 10 mEq products entered. Neither the new entrants nor the existing generics constrained K-Dur 20. Instead, in the absence of a generic equivalent, Schering's K-Dur 20 prescriptions increased, both in absolute terms and relative to other potassium products, until generic K-Dur 20 entered the market in September 2001. (Figure 1); CPF 976-78; CX 1389 at SP 2300016.

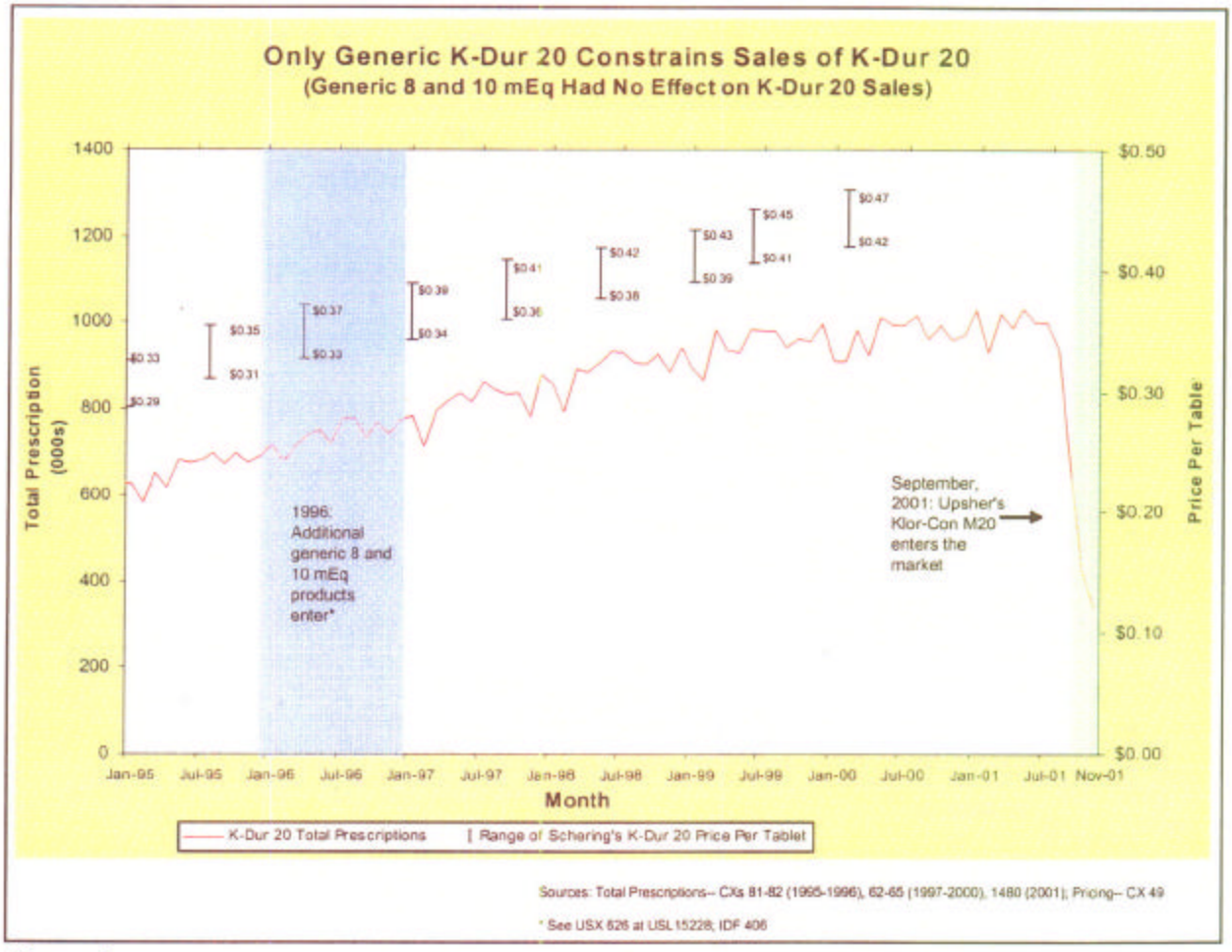

Figure 1

Similarly, Schering enjoyed uninterrupted growth in its net sales and product margins, despite the entry of other generic products. (Figure 2).

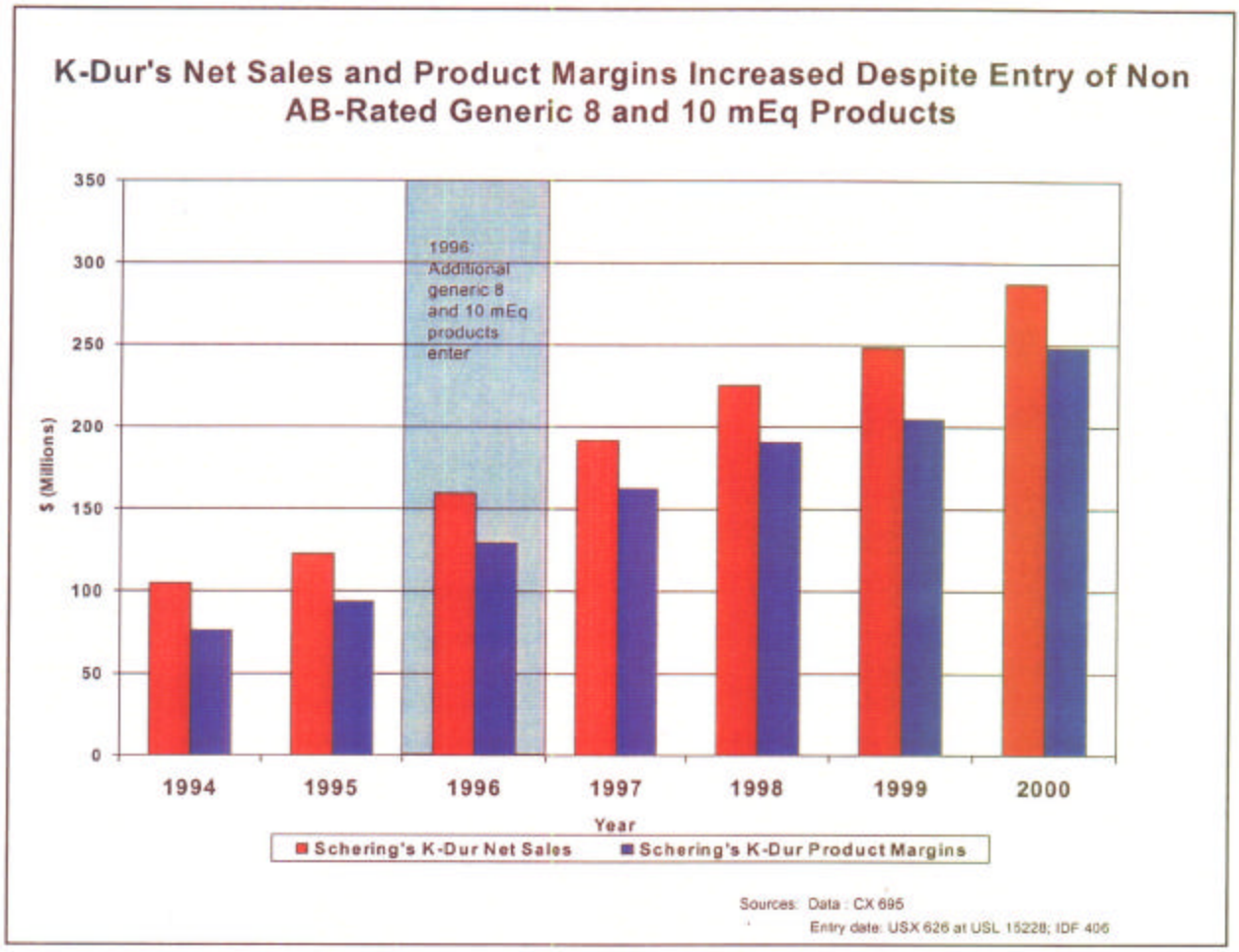

Figure 2

Although entry by generic 8 and 10 mEq potassium products did not diminish K-Dur 20 sales, Schering knew that a generic counterpart to K-Dur 20 would dramatically erode its

revenues. For example, in June 1997, fearing generic entry, Schering predicted that its K-Dur revenues would drop from $200 million to just over $100 million in two years.[6] (Figure 3).

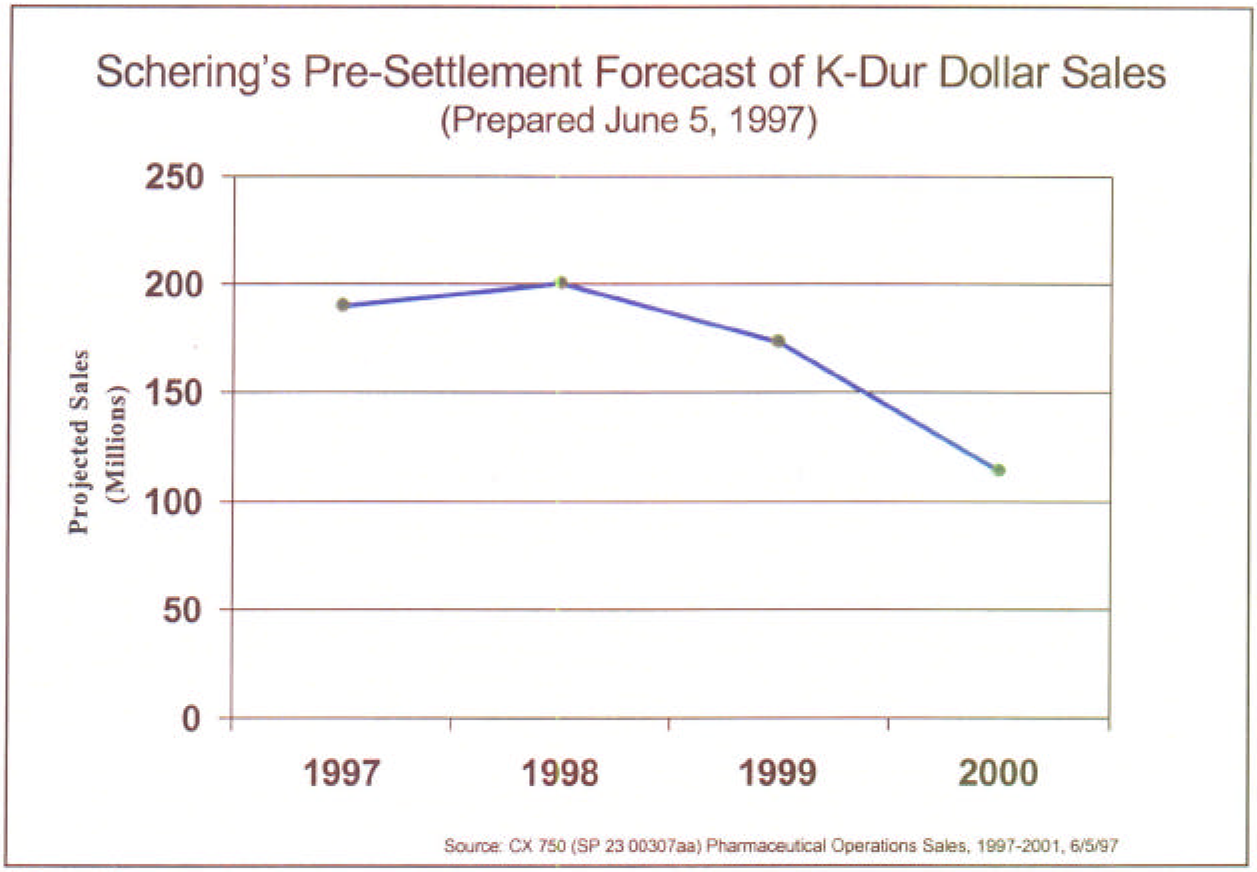

Figure 3

Indeed, Schering's various projections consistently reached the same conclusion – that generic K-Dur 20 entry would eviscerate Schering's K-Dur sales.[7]

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[6] Schering's forecasts were for K-Dur 10 and 20 combined. K-Dur 20 represented over 83% of K-Dur prescriptions. CX 62 (based on IMS Health data). [redacted]

[7] *See, e.g.*, [redacted]; CX 128; CX 133.

Empirical research shows that the rapid sales erosion that Schering predicted reflects a general phenomenon in the pharmaceutical industry.[8] Within the first full year after launch of a generic product, branded drugs lose an average of 44% of their sales to the generic.[9] State laws play an important role in this process. Virtually all states encourage generic competition through laws that allow pharmacists to dispense an AB-rated generic drug when presented with a prescription for its branded equivalent, unless the physician directs otherwise. In contrast, "therapeutic interchange" – the dispensing of an alternative product that is not an AB-rated generic, but that the pharmacist deems to be therapeutically equivalent – is generally permitted only upon the prescribing physician's approval. CPF 34.

Many health plans, Medicaid, and other state public assistance [illegible] capitalize on the easy substitution created by state pharmacy laws and encourage or insist upon use of generic versions of branded drugs whenever possible. CPF 39, 42-49.

3. The threat of generic entry

a. Schering's limited patent protection

Although Schering had a patent covering K-Dur 20 that did not expire until 2006, it did not expect its patent to actually prevent all generic entry. K-Dur's active ingredient, potassium chloride, is in common use and unpatentable. The patent covering K-Dur 20 (the '743 patent) relates only to the type and viscosity of the material that coats the potassium chloride crystals,

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[8] *See* articles cited note 44, *infra.*

[9] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, xiii (1998).

which provides the tablet with its extended-release mechanism. A generic manufacturer would therefore not infringe the '743 patent if it used a coating not covered by the patent. CPF 67-73.

As a result, Schering predicted that generic entry would occur before patent expiration in 2006. CPF 75-78, 81-82. Internal business documents warned that "direct generic competition is expected" and might arrive by 1997 or 1998.[10] By 1997, Schering was purchasing packaging supplies and making plans to launch its own generic though its Warrick unit – something it would do only in response to generic entry. CX 682; CPF 79-82.

b. Hatch-Waxman

The statute governing approval of generic drugs, referred to as "the Hatch-Waxman Amendments," encourages companies to challenge invalid patents or to d[illegible]ound valid patents. A generic applicant files an Abbreviated New Drug Application ("ANDA") to establish that its product is bioequivalent to its branded counterpart. The first company that seeks FDA approval to market a generic alternative to a branded drug while it is still covered by a patent, and certifies to the FDA that the patent in question is invalid or not infringed (known as a "Paragraph IV certification"), is eligible for a 180-day market exclusivity period. CPF 27. No other generic manufacturer may obtain FDA approval to market its product until the first filer's exclusivity period has expired. CPF 902-03.

c. Upsher and AHP seek to compete

By late 1995, Schering's K-Dur 20 revenues were threatened because Upsher and AHP (through its ESI-Ledêrle unit) each had sought FDA approval to market generic K-Dur 20. CPF 92, 815. Each certified to the FDA that its product did not infringe Schering's patent. CPF 93,

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[10] CX 13 at SP003044.

815. Upsher was the first to file an ANDA and, thus, was eligible for the Hatch-Waxman exclusivity period. CPF 926.

Schering promptly sued Upsher and AHP for patent infringement, triggering an automatic 30-month stay on FDA approval of the ANDAs. CPF 98, 822.

4. The parties negotiate settlement agreements

In late 1996, Schering and AHP began settlement discussions. Schering's first proposal was for AHP to abandon its generic K-Dur 20 and instead receive compensation from Schering for promoting K-Dur 20. CX 459; CX 466. Thus, in this "co-promotion" arrangement, Schering expressly offered to pay AHP compensation in exchange for not competing.

In March 1997, AHP's counsel rejected "co-promotion" and proposed that Schering "make an appropriate payment" to AHP, in return for which, AHP would "forebear from entering the market" until "some subsequent time (for example, in 2002)," an offer that Schering rejected. CX 458; CX 459.

Also in March 1997, Upsher received tentative FDA approval for its generic K-Dur 20 product. CPF 121. [redacted][11] Upsher also took steps needed to prepare for the

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[11] [redacted]

launch of its product, including purchasing raw materials and reserving time with its contract manufacturer for production of commercial scale quantities. CPF 132-40.

One month before the June 1997 trial date, Schering and Upsher began to negotiate a settlement. CPF 190. Upsher president Ian Troup told Schering executive Martin Driscoll that Upsher's launch of its generic K-Dur 20 could "open a flood gate" of generic competition to K-Dur 20. CX 1529 at 88 (Troup IH). Schering knew that Upsher was the first to file an ANDA with a Paragraph IV certification, and thus was eligible for the Hatch-Waxman exclusivity period. While it was unclear at that time whether Upsher would lose its exclusivity rights if it did not successfully defend the patent litigation (CPF 902-10), there was no doubt that if the parties did not settle, and Upsher prevailed, Upsher's exclusivity rights would [illegible]r be a barrier to entry by others seeking to compete with K-Dur 20. CPF 903.

Mr. Troup wanted to be paid to stay off the market (CX 1529 at 111-12 (Troup IH)), and he asked for $60 million. CPF 200-02. In an "Executive Summary," Schering noted it would need to provide Upsher with a "royalty stream" until its generic was allowed on the market, and observed that one way to do this would be to "[r]eview [Upsher's] portfolio and purchase pipeline products or in-line portfolio for [Schering] to promote." CX 283 at SP018780, 81. Both parties estimated Schering's loss if generic entry occurred in 1998 (CX 128 at SP2300325a; CX 150 at USL08536, 38, 39; CPF 96-97), and Upsher's loss if it stayed off the market until 2001. CX 283; CPF 210, 214, 216. Schering calculated the "Estimated value of K-Dur 20 generic to [Upsher]" assuming a 1998 launch, and estimated the net present value of Upsher's lost revenues from withholding its generic from the market through 2001 at $45-55 million.

CX 283 at SP018781. Schering's 1997 earnings on K-Dur 20 exceeded $170 million. CX 1389 at SP2300016.

5. Schering and Upsher Settle

On the eve of trial, the parties settled. Schering agreed to pay Upsher $60 million, in three unconditional payments over two years (the discounted value of approximately $53-55 million (CPF 216)). Upsher agreed not to launch a generic product that was AB-rated to K-Dur 20 for over four years, until September 2001, and not to assist AHP in its patent litigation with Schering. The parties agreed to a bundle of licenses from Upsher to Schering, which granted marketing rights outside North America for Niacor-SR (a sustained-release niacin product) and other products. In addition to the $60 million in non-contingent pay[illegible]alled "up-front royalty payments," Schering also agreed to pay Upsher conventional milestone and royalty payments. CX 348.

The agreement required approval by Schering's Board of Directors. CX 348 at ¶ 9. Schering's managers told the Board that Upsher would not settle the patent litigation without the $60 million non-contingent payment, explaining that the payment terms were dictated by Upsher's desire for a "guaranteed income stream" that would compensate it for giving up what Upsher believed it would earn from its generic K-Dur 20 if it won the lawsuit. CX 338 at SP1200270 (providing Upsher a guaranteed income stream for the next twenty-four months was a "prerequisite of any deal"). Board members were never shown the settlement agreement. After about a fifteen-minute discussion, they voted to approve the management recommendation on June 24, 1997. CPF 220.

With the Upsher agreement, Schering managers knew K-Dur 20 sales had "a new lease on life." CX 20 at SP004040 (1998 K-Dur 20 Marketing Plan). New forecasts of continued sales growth supplanted the previously dire predictions of imminent losses due to threatened generic entry. (Figure 4).

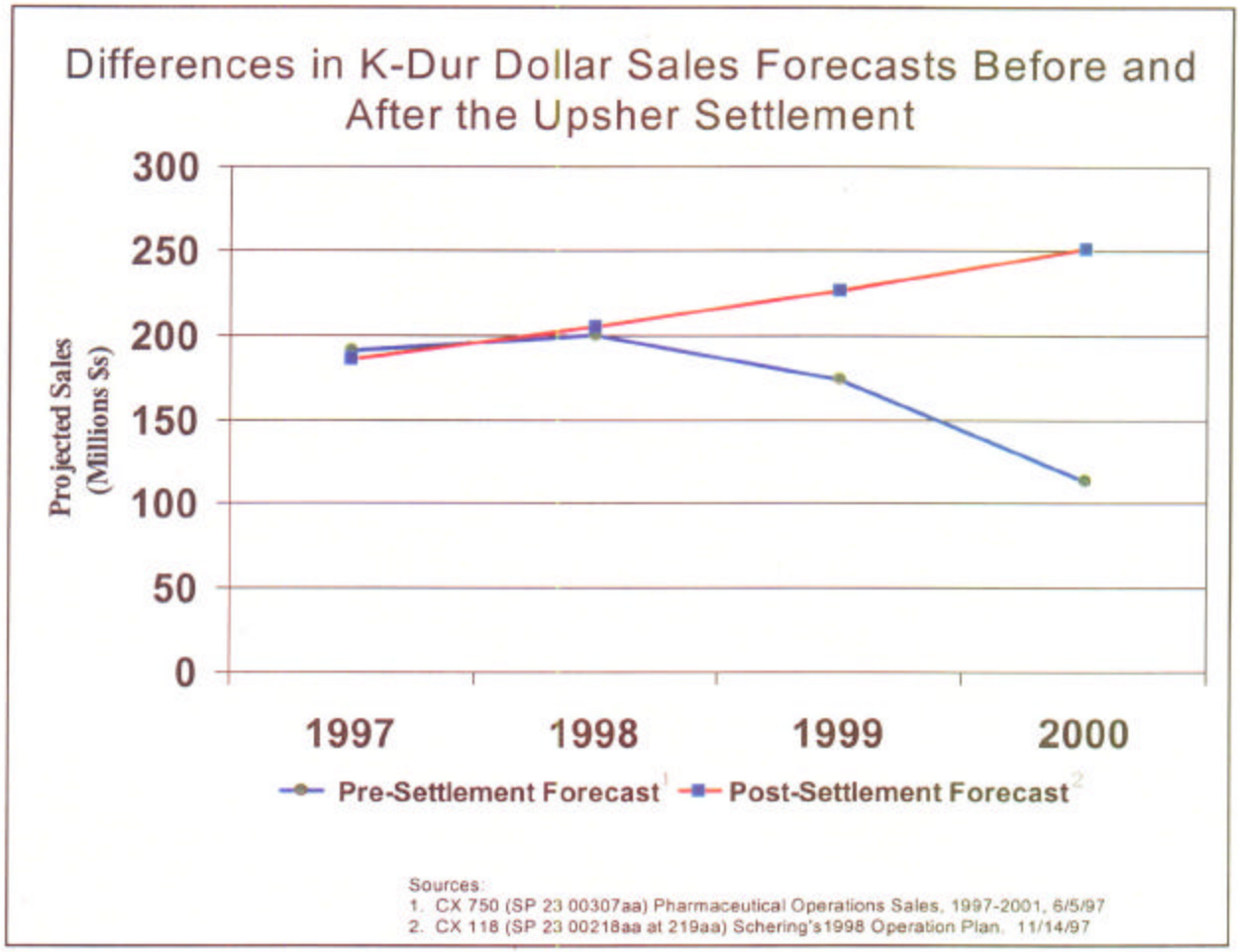

Figure 4

6. Schering and AHP Settle

After Schering settled with Upsher, AHP insisted that it could not meaningfully negotiate any settlement without knowing the Upsher settlement terms. CX 462; CPF 863. After receiving

the terms of that settlement, AHP provided Schering with estimates of what AHP would lose by staying off the market for several years. CX 461. AHP would have no lost revenues, however, if its ANDA never got FDA approval, and (unlike Upsher), AHP had not yet received tentative FDA approval. Thus, as negotiations proceeded, Schering demanded and received assurances that AHP's product was approvable.[12]

In the meantime, legal developments concerning the Hatch-Waxman 180-day exclusivity period increased the threat of AHP's entry. Court decisions increased the likelihood that Upsher lost its exclusivity rights by settling or that Upsher's exclusivity could be triggered by a court decision holding that another company's ANDA product did not infringe Schering's patent. These cases intensified Schering's uncertainty as to whether the Upsher agreement would block AHP's entry. CPF 911-22.

AHP refused to settle, however, without a substantial payment. Tr. 12:2720-21 (Driscoll); CPF 857-58, 874. The parties eventually settled the case with an agreement similar in several respects to the one Schering entered into with Upsher six months earlier. They agreed in principle in January 1998, followed by a final agreement in June 1998, under which Schering paid AHP $15 million – $5 million up-front and $10 million conditioned on AHP's obtaining tentative FDA approval by June 1999 (and lesser amounts if FDA approval came later). In return, AHP agreed not to launch its generic product until 2004. AHP also agreed to other restrictions, including prohibitions on conducting bioequivalence studies relating to K-Dur 20, selling more than one generic K-Dur 20 product between 2004 and 2006, and transferring its

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[12] CX 468 at AHP0500226; CX 469; CX 474 at SP1300633.

ANDA. CX 484. Finally, in a separate agreement, Schering purchased a license to two AHP generic products for an additional $15 million. CX 480.

AHP received tentative FDA approval in May 1999 (CX 612), and therefore received the full $15 million due under the settlement agreement. AHP has adhered to its promise not to introduce any generic K-Dur 20 before 2004. CPF 883-86.

7. Upsher Enters in September 2001

The $60 million non-contingent payments called for under the Schering/Upsher agreement were guaranteed regardless of whether Upsher pursued development of Niacor-SR. In fact, Schering made its scheduled payments through June 1999 (CPF 224, 255, 257), even though by October 1997, Upsher had decided to devote only "minimal activity" towards seeking approval of Niacor-SR. CPF 695.

Upsher kept its promise not to launch its product until September 2001. When it did finally enter, at about half the price of K-Dur 20,[13] Upsher's Klor Con M20 (Upsher's generic version of K-Dur 20) had a more drastic effect on Schering's K-Dur 20 sales than had been projected. After only three months of generic competition, Klor Con M20 accounted for over 70% of new 20 mEq prescriptions (CX 1480 at SP 089837) and over 60% of all 20 mEq prescriptions. (Figure 5).

[13] Schering Second Admissions, No. 226; CPF 990.

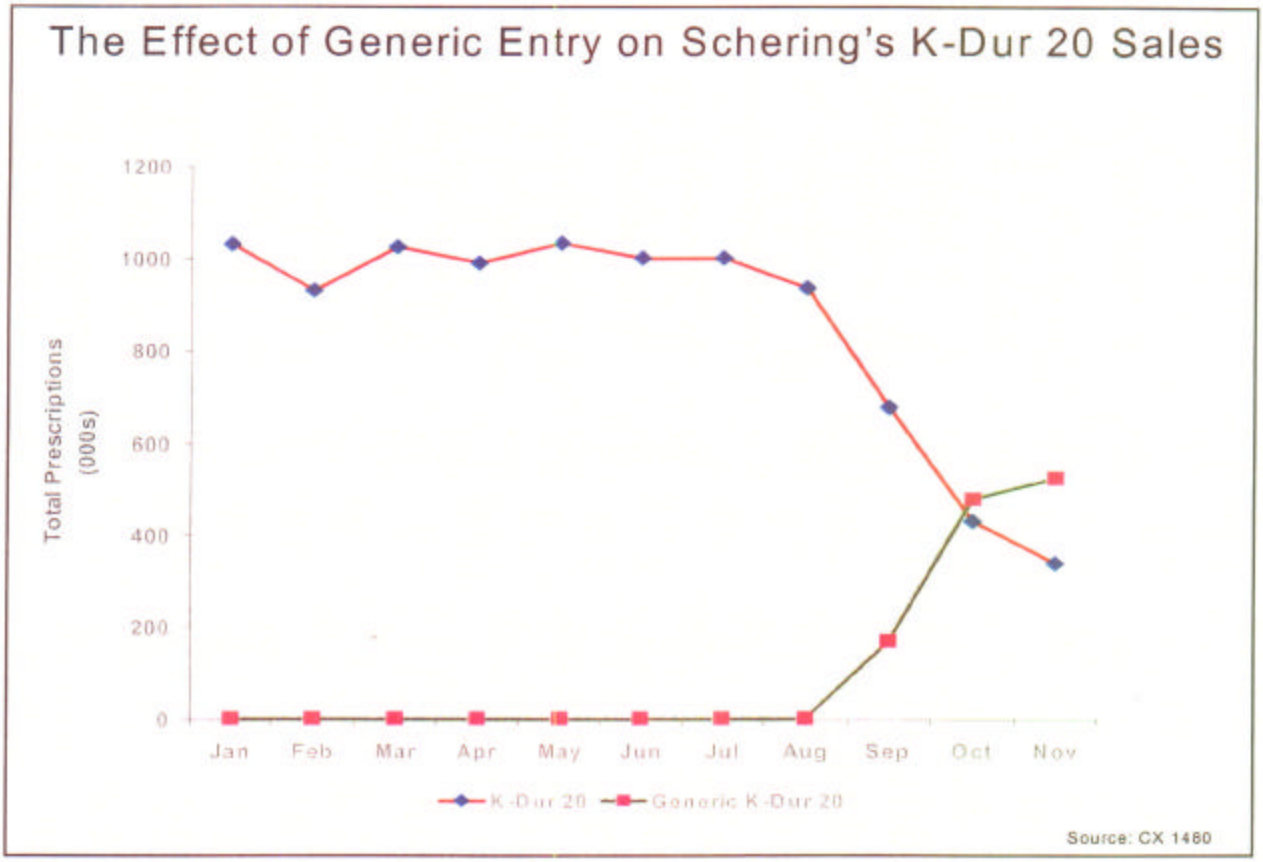

Figure 5

B. Proceedings Below

The complaint, issued March 30, 2001, charges that Schering made large cash payments to Upsher and AHP to induce them to forebear launching any generic competition to Schering's K-Dur 20 for several years. The complaint alleges that, by virtue of these agreements, all respondents violated the FTC Act, and, in addition, that Schering's actions amount to unlawful monopoly maintenance. AHP was withdrawn from adjudication in October 2001 to permit consideration of a proposed consent agreement, which became final in April 2002. Trial against the other two respondents commenced January 23, 2002, and concluded March 22, 2002.

In an initial decision filed June 26, 2002, ALJ D. Michael Chappell dismissed the complaint. He held that Schering's $60 million non-contingent payment to Upsher was entirely for licenses to Upsher's products. Though he acknowledged language in Schering's written agreement with Upsher that expressly states the payments were for obligations that included Upsher's promise not to launch its generic until September 2001, he deemed the parties' use of the term "royalty" in connection with the $60 million in non-contingent payments to be controlling in his reading of the agreement. ID at 111.

The ALJ also found that "only $15 million of the $30 million [Schering agreed to pay AHP] were royalty payments" (IDF 370), but never said what the other $15 million was for. Later, however, he stated that complaint counsel failed to prove "that any payment was not for fair value." ID at 112.

The ALJ further held that complaint counsel could not prevail without proof that Upsher or AHP could have been on the market prior to the expiration of Schering's patent. ID at 104-05. Noting that the evidence confirmed complaint counsel's contention that the likely outcome of the patent disputes cannot be reliably predicted, ALJ Chappell concluded that this inability to prove the outcome of the patent cases was fatal:

> Complaint Counsel argues that antitrust laws prohibit Schering from paying Upsher-Smith and ESI to stay off the market. However, Complaint Counsel has not established that Schering paid Upsher-Smith and ESI to stay off the market because Complaint Counsel has not proved that Upsher-Smith or ESI could have even been on the market prior to the expiration of the '743 patent. ID at 104.

Finally, the ALJ ruled there had been no showing that Schering had monopoly power before it faced competition from generic K-Dur 20. He did not address the evidence of the dramatic impact that generic entry would have and did have on Schering's K-Dur 20 sales.

Instead, finding that there are various other forms of potassium that "may be substituted" for K-Dur 20 (ID at 89), he concluded that complaint counsel needed to demonstrate the indicia for a submarket set forth in *Brown Shoe v. United States*, 370 U.S. 294 (1962), and that we had failed to do so.

QUESTIONS PRESENTED

1. Was at least some of the $60 million in non-contingent payments from Schering to Upsher paid as compensation for Upsher's agreement to stay off the market until September 2001?

2. Did Schering pay AHP $15 million to stay off the market until 2004?

3. Are Schering's agreements to settle patent infringement litigation brought against Upsher and AHP – by means of payments to secure their promises to stay off the market for several years – unreasonable restraints of trade in violation of Section 5 of the FTC Act?

4. Did Schering have monopoly power prior to the entry of generic K-Dur 20?

5. Do the challenged agreements constitute unlawful monopoly maintenance and conspiracies to monopolize in violation of Section 5 of the FTC Act?

SUMMARY OF ARGUMENT

Generic drugs offer consumers access to more affordable medications critical to their health and well-being. Both the federal government and the states have enacted laws to promote consumer access to low-cost generic alternatives, in order to encourage competition in pharmaceutical markets, aid consumers, and help contain rising health-care costs. Consumer savings from generic drug competition, however, also mean lower profits for the makers of branded pharmaceuticals.

The evidence shows that Schering sought to protect itself against the dramatic loss it would suffer when generic K-Dur 20 entered by paying Upsher and AHP to stay off the market

for several years. The ALJ's conclusion that no part of Schering's payments to Upsher were for the 2001 entry date is contrary to the record evidence. His failure to find that $15 million of Schering's payments to AHP was in consideration for AHP's agreement to stay off the market until 2004 likewise cannot be sustained, given the express terms of the agreement. (Part I).

Schering's agreements with Upsher and AHP constitute unlawful horizontal restraints whether judged under a *per se* standard or under a closer rule of reason examination. Paying a potential competitor not to enter the market is presumptively anticompetitive. The fact that these agreements were entered into in settlement of patent litigation does not in itself provide a justification, or reduce their potential for substantial harm to competition. While patent settlements can promote competition, they can also be vehicles for anticompetitive conduct. This principle is evident from the Supreme Court's decisions in *United States v. Masonite Corp.*, 316 U.S. 265 (1942), *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963), and other cases holding agreements settling patent disputes unlawful. (Part II.A).

Moreover, the record evidence establishes that these agreements had anticompetitive effects. First, Upsher's generic K-Dur 20 entry benefitted consumers by providing a low-cost alternative to K-Dur 20. Delaying such entry, therefore, would harm consumers. Second, Schering's substantial payments to its would-be generic entrants induced them to accept a later entry date than the parties anticipated would result from continuing the litigation, or from a settlement without a payment. Finally, agreements anticompetitive at the time entered into are illegal without proof of what would have happened in the market absent the challenged conduct. (Part II.B).

Respondents' contention that the agreements were procompetitive because they guaranteed an entry date before patent expiration is not a cognizable antitrust justification. The notion that competitors can, through a mutually advantageous arrangement, set a schedule that guarantees generic entry is no more legitimate than an argument that consumers would be better off with guaranteed prices fixed by competing sellers. Respondents' claim that payments may be necessary to reach procompetitive settlements is merely a post-hoc rationalization. While their economic experts theorize about possible circumstances in which a payment for a future entry date might not result in delayed entry, each theory actually is a road map to anticompetitive conduct, showing that the parties will always be better off if the incumbent pays more and the entrant agrees to an anticompetitive entry date. In any event, no evidence suggests that respondents' theories could explain the payments challenged in this case – their economic experts never attempt to apply their theoretical models to the facts of this case – or even suggest that the type of payment at issue here has ever been used to reach a procompetitive settlement. (Part II.C).

Anticompetitive agreements among competitors are unlawful even when they do not threaten to create or maintain a monopoly. In this case, however, the agreements also amount to acts of monopolization and unlawful conspiracies to monopolize. Prior to generic entry, Schering had monopoly power and the agreements preserved that power. Generic K-Dur 20 had a unique ability to takes sales from Schering's product, and lower the average market price paid for 20 mEq potassium chloride tablets and capsules. The ALJ insisted, however, that Schering could not possibly have had a monopoly – notwithstanding the abundant direct evidence that it did – because reliance on the *Brown Shoe* indicia (which are merely proxies) to define a market

including all potassium chloride products led him to disregard the hard facts about the effect of generic K-Dur 20's entry. (Part III).

In addition to reversing the initial decision, the Commission should vacate four rulings by ALJ Chappell that excluded significant rebuttal evidence. In one instance, the ALJ allowed Upsher to use a private confidentiality agreement to persuade a third-party witness to stop cooperating with complaint counsel. In another, he excluded expert testimony by Professor Bresnahan that would have assisted the Commission as the trier of fact in understanding data in the record concerning prescription and substitution patterns. He twice ignored well-established legal standards that govern when to exclude evidence as a penalty for disclosures made after scheduling order deadlines. The current record proves the violations here, but these erroneous rulings not only set harmful precedents for ALJs in future cases, but also deprive the Commission and any reviewing court of a record that is as complete as possible. The Commission should therefore vacate these erroneous rulings and reopen the record to take testimony that improperly was excluded. (Part IV).

ARGUMENT

I. The Evidence Shows that Schering Paid Upsher and AHP to Secure Their Agreements Not to Compete until a Future Date

A. Schering Paid Upsher Not to Compete Until September 2001

The material facts relating to Schering's agreement with Upsher are, for the most part, not in dispute. Schering was acutely aware that K-Dur 20's profits would plummet once generic competition arrived, making any delay in generic entry extremely valuable. CPF 83-84. Upsher threatened to enter with generic K-Dur 20 (IDF 125-26); if it did, consumers would benefit from the low-cost alternative to Schering's product. IDF 19-21; CPF 28. Schering sued Upsher, claiming that Upsher's product infringed the '743 patent. IDF 127. Upsher denied infringement, maintaining that it successfully had designed around Schering's patent. IDF 130.

On the eve of trial, the parties settled. IDF 127, 155. Several critical facts about this agreement also are not in dispute:

- Schering paid Upsher $60 million and Upsher agreed not to launch its generic K-Dur 20 product until September 2001, (IDF 152-57; CPF 171, 174);
- Upsher abided by this agreement, (IDF 94); and
- Generic competition to K-Dur 20 did not occur until the agreed-upon date, more than four years later. (IDF 94).

The only material factual issue in dispute is whether the entire $60 million payment was a payment for the Niacor-SR license, as respondents contend and the ALJ found, or whether at least some part of it was for the agreed-upon entry date.[14]

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[14] Although Schering also obtained licenses to four Upsher products in addition to Niacor-SR, Schering does not claim that the $60 million payment was for any of these other

Respondents' position is not credible. It is contrary to the testimony and contemporaneous documents about the settlement negotiations; it is refuted by the terms of the agreement, which explicitly state that the payment was, in part, consideration for Upsher's promise not to compete until September 2001; and it is inconsistent with virtually all of the record evidence – with the exception of respondents' after-the-fact self-serving trial testimony. But as the Supreme Court made clear in *United States v. United States Gypsum Co.*, trial testimony that is contradicted by contemporaneous documents should be given little weight.[15] Nonetheless, the ALJ repeatedly relies on this self-serving testimony in adopting respondents' position that the $60 million payment was entirely for the Niacor-SR license, even when that testimony is contradicted by the parties' contemporaneous business records, prior sworn statements,[16] and common sense.

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products. CX 1510 at 40 (Kapur IH) ($60 million payment was for Niacor-SR, and the other "ancillary" products were just "thrown in"); Schering Br. at 2 ("Complaint Counsel has the burden of proving that the $60 million payment was *not* for the Niacor license"); *see also* CPF 245-46, 312.

[15] 333 U.S. 364, 396 (1948); *see also Adolph Coors Co.*, 83 F.T.C. 32, 185 (1973) ("It is well established, however, that little weight can be given to testimony which is in conflict with contemporaneous documents"); *Toys "R" Us, Inc.*, 126 F.T.C. 415, 567 n.39 (1998) (rejecting "self-serving" testimony contradicted by contemporaneous documents).

[16] The record includes transcript excerpts from ten investigational hearings of Schering and Upsher employees. These excerpts were admitted by ALJ Chappell as the non-hearsay admissions of a party-opponent, to be used against the party whose witness provided the testimony. Pretrial Hearing, 4:297-98 (Jan. 23, 2002). ALJ Chappell never set forth the scope of what it meant to use the investigational hearings "against" a particular party. Nonetheless, the ALJ virtually ignored this testimony in making his findings of fact, citing them only twice, on trivial points. *See* IDF 151, 220. The ALJ's failure to rely on an entire category of relevant, reliable, and material evidence undermines his factual findings. The investigational hearing transcripts in evidence are the verbatim statements of the witness, taken under oath, with counsel present to make objections and conduct cross-examination. The Commission should rely on this relevant record evidence in its decision.

ALJ Chappell, for example, found it significant that no Schering or Upsher witnesses admitted at trial that Schering's payment to Upsher was for delayed generic entry. ID at 162. That respondents' employees would deny being a party to an illegal agreement is neither surprising nor significant.[17] This case does not stand or fall on whether respondents made testimonial confessions; rather, it is built, as are most antitrust cases, on the totality of the evidence.[18] That evidence, described below, contradicts respondents' self-serving statements and demonstrates that Schering paid Upsher millions of dollars to secure Upsher's promise to keep its generic K-Dur 20 off the market until September 2001.

We note at the outset that to reject respondents' contention that the entire $60 million payment was for Niacor-SR, the Commission need not conclude the license was a "sham," or that it lacked any value to Schering. Rather, the Commission need only find that, along with rights to Niacor-SR, Schering also bought and paid for Upsher's commitment to keep its generic K-Dur 20 off the market until September 2001.

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[17] *Bond Crown & Cork Co. v. FTC*, 176 F.2d 974, 979 (4th Cir. 1949) ("[T]he [C]ommission [is not] required to accept the denials of those charged with the conspiracy merely because there is no direct evidence to establish it").

[18] *United States v. Falstaff Brewing Corp.*, 410 U.S. 526, 536 (1973) ("[C]ircumstantial evidence is the lifeblood of antitrust law"); *High Fructose Corn Syrup Antitrust Litig.*, 2002 U.S. App. LEXIS 11940 at *27 (7th Cir. June 18, 2002) ("[M]ost [antitrust] cases are constructed out of . . . circumstantial evidence"); *JTC Petroleum Co. v. Piasa Motor Fuels, Inc.*, 190 F.3d 775, 779 (7th Cir. 1999) (inferences drawn from circumstantial evidence can provide proof of antitrust violation).

1. The evidence of the negotiations shows Schering's payment was in exchange for Upsher's promise to stay off the market

Testimony from fact witnesses and contemporaneous business documents about the settlement negotiations establish that (i) Upsher repeatedly demanded multi-million dollar payments to keep its generic product off the market; (ii) these demands for cash were specifically tied to the amount Schering could lose in K-Dur 20 sales if Upsher prevailed in litigation, and entered the market; (iii) Schering knew that it must meet Upsher's demands for "cash" to settle the litigation; and (iv) Schering's $60 million payment to Upsher matches the generic K-Dur 20 revenues Upsher would forego by keeping its product off the market until 2001. From these facts the Commission should draw the plain inference: Schering paid Upsher for its promise to stay off the market until 2001.

a. Schering recognized the benefit it would realize by paying Upsher to stay off the market

Schering expected that generic entry to K-Dur 20 would take place well before the patent's expiration date in 2006, and could occur as early as 1997. CPF 75-82. Because generic K-Dur 20 would be priced much lower than Schering's brand (CPF 29-32), Schering was acutely aware of how quickly its K-Dur 20 profits would fall once generic competition arrived. According to one projection, Schering expected that entry of generic competition would take nearly 50% of K-Dur 20 revenues within four months.[19] Such lost sales would reduce Schering's profits by $7 million a month. Tr. 3:531-32 (Bresnahan). The prospect of such substantial losses

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[19] CX 133 at SP2500004; Tr. 3:442-46 (Bresnahan). Schering's other forecasts predict a similar impact. *See, e.g.*, CPF 84; CX 122F at SP2300316.

gave Schering a powerful incentive to accede to Upsher's demands. Tr. 3:424-29 (Bresnahan); CPF 1150-58.

b. Upsher demanded cash and sought a percentage of Schering's potential lost K-Dur 20 revenues

The testimony of three Schering officials participating in the negotiations is clear and consistent: Ian Troup, Upsher's president and sole negotiator, repeatedly asked Schering to "pay Upsher-Smith to stay off the market" (CX 1509 at 32-33 (Hoffman dep)); he was "very insistent" that Schering provide Upsher with "an up-front payment and cash" as part of any settlement (CX 1531 at 88-89 (Wasserstein IH)); he "wanted a payment to come off the market, for them to stay off the market" (CX 1494 at 71 (Driscoll IH)); and he was "very forceful" in this demand, and would not "move off [this] position." *Id.* at 65-66, 71; *see also* CPF 200-02.

Upsher's demand for money had nothing to do with Niacor-SR. It was all about the generic K-Dur 20 sales Upsher would forego by staying off the market, as well as the K-Dur 20 sales Schering stood to lose if Upsher entered. In Mr. Troup's own words:

> I'm going to lose revenue by not coming onto the market and I want – as well as this 2001 date, what am I going to do about my lost revenue before, so are you going to compensate me for this theoretical lost revenue? CX 1529 at 111-12 (Troup IH).

Schering's negotiators understood Troup's meaning: He was "looking for a revenue stream to replace" Upsher's generic version of K-Dur 20, and "if his [generic K-Dur] entry was delayed in terms of the revenue stream that he hoped to make [that] up." CX 1510 at 104 (Kapur IH); CX 1511 at 19-20 (Kapur dep). He demanded a "payment in the neighborhood of $60 to 70 million." CX 1494 at 65-66 (Driscoll IH). Troup had predicted the "impact" that Upsher's generic entry would have on the performance of Schering's K-Dur 20 sales, and his $60 to $70

million demand to settle the litigation was based on a percentage of that anticipated impact. Tr. 2:320-21 (Driscoll IH) (if Upsher "prevailed in the litigation . . . a generic to K-Dur 20 would have X impact on Schering in terms of the performance of K-Dur 20 in the market and that he felt they should receive a payment that was a percentage of that impact"). Simply put, Upsher wanted a share of Schering's profits for staying off the market, and if it did not get it, Upsher threatened to "open up a flood gate" of generic competitors to K-Dur 20. Tr. 2:302-03 (Troup IH).

c. Schering knew it would have to pay Upsher to stay off the market and determined how much to pay by calculating Upsher's foregone revenues

Schering understood that Upsher required a "guaranteed income stream" to compensate it for keeping its generic K-Dur 20 product off the market. While seeking approval for the proposed agreement, Schering management told its Board of Directors precisely that: Upsher was seeking an "income stream to replace the income that Upsher-Smith had anticipated earning" if it won the litigation (CX 338), and this compensation was a "prerequisite" for any settlement of patent litigation:

> **Payment Terms**
> In the course of our discussions with Upsher-Smith they indicated that a prerequisite of any deal would be to provide them with a guaranteed income stream for the next twenty-four months to make up for the income that they had projected to earn from the sales of Klor Con had they been successful in their suit.

CX 338 at SP1200268-70; *see* CPF 219.

Another Schering document, titled "Executive Summary," is the company's blueprint for dealing with Upsher. CX 283. It notes not only the need to compensate Upsher, but also states explicitly that this compensation be tied to the absence of generic K-Dur 20 competition:

> [a]ny deal with Upsher Smith should be lucrative and provide them with a guaranteed revenue stream of approximately $25-20 Million per year until another K-Dur ANDA is approved.

CX 283 at SP018780. In other words, payment should last only for so long as Schering continued to earn high profits absent generic competition. Once generic competition arrived, the "royalty stream" should stop: "We could then allow Upsher Smith to market their own product and discontinue any royalty stream after that time." *Id.* The "Executive Summary" then calculates the "Estimated Value of K-Dur 20 generic to [Upsher]" through 2001, assuming a 1998 launch. *Id.* at SP018781. It estimates that if Upsher withheld its product through 2001, it would lose $45-55 million in net present value. *Id.*[20]

d. Schering decided to transfer cash to Upsher by purchasing pipeline products

Schering knew that any K-Dur 20 patent settlement had to meet Upsher's repeated demands for cash.[21] Moreover, Schering already had decided that it was willing to compensate a generic if the arrangement would keep its product off the market, having just made such an offer to AHP in its "co-promotion" proposal. CPF 854. But Schering knew from its counsel that it faced heightened antitrust risk if it simply made a naked payment to keep Upsher's generic product off the market. CPF 225. As with the co-promote arrangement, therefore, Schering sought a mechanism that would dress up the payment. The strategy that Schering ultimately chose is previewed in the "Executive Summary":

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[20] The ALJ ignored this document in his decision. Schering admits that the document comes from its files but disavowed knowledge of its authorship.

[21] Tr. 2:348 (Hoffman IH) ("Upsher-Smith had a need for income"); CX 1508 at 76 (Hoffman IH) (Upsher needed the "type of arrangement" that would provide "some revenue now," in order to settle the litigation); CPF 225-28.

> Review [Upsher's] portfolio and purchase pipeline products or in-line portfolio for [Schering] to promote. CX 283 at SP018780.

Tellingly, Schering's eventual agreement with Upsher tracks the model outlined in the "Executive Summary" virtually to the letter. Schering licensed a bundle of products from Upsher, including Niacor-SR. It arranged to pay Upsher $60 million over a two-year period.[22] The discounted value of these $60 million payments is dead on with the value of Upsher's lost revenues set forth in the "Executive Summary." CPF 216. In exchange for receiving the revenues from Schering that Upsher otherwise expected to get from its generic K-Dur 20 sales, Upsher agreed to forego competition with Schering until September 2001.

2. The terms of the agreement show the payment was for the entry date

The unambiguous terms of the agreement explicitly establish that Schering's commitment to pay $60 million is inseparable from Upsher's commitment to stay off the market for four years.

a. Schering's $60 million payment was, at least in part, in consideration for Upsher's agreement not to enter until September 2001

The agreement, at paragraph 11, explicitly states that Schering's payments – including the so-called "up-front royalty" payments of $60 million over two years – are "[i]n consideration for

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[22] Schering's approach to the Niacor-SR licensing deal further demonstrates that the $60 million payment was, in part, for the 2001 entry date. Instead of determining the value of the licensing opportunity first, and then negotiating a price based on that value, Schering knew how much it was going to pay Upsher even *before* it began its Niacor-SR analysis. Schering Br. at 9 ("Mr. Kapur asked Mr. Lauda to evaluate the Niacor-SR license opportunity to see if it would be worth $60 million to Schering"); CX 1515 at 86 (Lauda IH) (Kapur "informed me that they had an opportunity to license . . . several products, from Upsher . . . and could I perform an assessment of that against a background that the value would probably – the payment would probably be about $60 million.").

the licenses, rights and obligations described in the [ten preceding] paragraphs,"[23] – one of which sets forth Upsher's obligation not to ,market its generic before September 2001. During cross-examination, Schering's in-house counsel did not "want to quibble" with the fact that the terms of the agreement show that the payment was, at least in part, consideration for Upsher's promise to stay off the market until 2001.[24]

ALJ Chappell acknowledged that paragraph 11 of the agreement provides that Schering's $60 million payments are "[i]n consideration" for the obligations described in the preceding paragraphs, including Upsher's obligation not to market generic K-Dur 20. IDF 156, 161. Nonetheless, the ALJ concluded that the $60 million was entirely for Niacor-SR. ID at 111. In so doing, the ALJ ignored the plain language of the agreement and the testimony of Schering's in-house counsel, choosing to rely instead on the self-serving trial testimony of Upsher's president whose testimony included, among other things, that the language of paragraph 11 must be some sort of "typo." Tr. 23:5555-56 (Troup). The Commission should set aside the ALJ's reading (ID at 111) of the agreement.

b. Upsher's obligation to stay off the market was conditioned on Schering's payments

If Schering's $60 million payments were entirely for the Niacor-SR license, as respondents claim, then there would be no reason to condition Upsher's obligation to stay off the

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[23] CX 348, Settlement and License Agreement (6/17/97) at USL03188.

[24] Tr. 15:3565-67 (Hoffman) ("Q: Okay. So on the face of this agreement, it's explicit and clear, is it not, that the money to be paid was paid at least in part for the settlement of the lawsuit? . . . A: Well, sir, if you read the language, you would realize that this also includes the milestone payments, which clearly weren't payment for any entry, but I don't want to quibble with you. I agree with your general remark.").

K-Dur 20 market on Schering's obligation to pay. But the agreement does precisely that. Schering's obligation to pay the $60 million terminates if a court invalidates the Niacor-SR license. CX 348 at ¶ 12. If that occurs, Upsher receives an immediate license to market its generic K-Dur 20 product. CX 348 at ¶ 3. Put simply, should Schering's obligation to pay be terminated, Upsher would be free to market its generic. Such a contingency makes sense only if at least some of Schering's $60 million payment was compensation for Upsher's promise not to compete.

c. Upsher would receive the payments so long as it kept its generic K-Dur 20 product off the market

Under the agreement, Upsher had to satisfy only one condition to receive the $60 million in payments: keep its generic K-Dur 20 off the market. CX 348. This would hold even if some act of God or other *force majeure* made the product licenses (including Niacor-SR) totally worthless. CPF 180. Indeed, the substantial payments supposedly for product licenses were not dependent on the development, regulatory approval, or marketability of these products. As Schering concedes, the $60 million in up-front payments were "guaranteed" (CPF 251), and it would be "stuck with the payments" even "if the [Niacor] product aborts for some reason." CPF 251.[25] And, as Upsher concedes, Schering's obligation to make these payments was not contingent on "anything." CPF 249. Thus, when Upsher abandoned the Niacor-SR project, Schering received no refund of the $28 million it had already paid Upsher, and was stuck paying Upsher another $32 million – which it did. CPF 331-33. Again, these terms show that some

[25] *See also* CPF 247-57.

portion of the payments was not just for Niacor-SR, but also for Upsher's agreement to stay off the market.

3. The ALJ's finding that the $60 million payment was entirely for the Niacor-SR license is contrary to the contemporaneous evidence

Despite the language of the agreement showing that the payment was, at least in part, consideration for Upsher's promise not to launch its generic product, respondents would have the Commission believe that Schering rejected Upsher's payment demands, and then fortuitously identified a product in Upsher's pipeline, which, by strange coincidence, purportedly turns out to be worth the same $60 million Upsher demanded to stay off the market. This story is too convenient and should be rejected as contrary to the record evidence.

a. $60 million was •••••••••••• as much as Schering had ever committed for a pharmaceutical license

A $60 million up-front license payment for Niacor-SR would have been the largest such payment in Schering's history; indeed, •••••••••••••• as much as it had ever paid. CPF 314-23. Respondents contended (and the ALJ found) that Schering paid $60 million entirely for a Niacor-SR license outside North America, even though:

- Schering expected Niacor-SR – if approved for sale – to be a minor drug with modest sales projections. Tr. 19:4434 (Lauda) (Schering's Executive Vice President testified that a product with no more than a $100 million in sales is "not a hugely successful product in the United States." Schering projected Niacor's annual sales to be only $45-149 million. CX 1044 at SP1600047.

- It was a product for which no other company (including Schering's European subsidiary (CX 844)) was willing to pay any up-front cash.[26]

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[26] Upsher spent the better part of six months shopping this product to 49 companies – "virtually everybody who is a pharmaceutical manufacturer or distributor outside of the United States." Tr. 28:6931 (Kerr). Of these, 45 companies either never responded or rejected the offer at any price. Only four companies expressed any interest, and none offered any up-front

- [redacted] In contrast to the ordinary due diligence carried out by Schering (CPF 485-86), Schering's entire Niacor-SR due diligence was conducted by a single employee in "[m]aybe a little bit more" than one day.[27]

- Despite having done less due diligence than ever before, Schering did not make its payments contingent on the completion of certain milestones (e.g., regulatory approval) – [redacted] – to manage the inherent risk of development, approval, or marketing failures. Instead, Schering committed to paying Upsher $60 million with no strings attached. CPF 324-33.[28]

- Thus, when Niacor-SR failed, all Schering had received for its $60 million was Upsher's promise not to market its generic K-Dur 20 until September 2001 – which, as shown above, was what Schering wanted in the first place, and was well worth the price.

b. *Schering had recently rejected a licensing opportunity for a similar, if not better, sustained-release niacin product*

Schering agreed to pay Upsher $60 million – purportedly for Niacor-SR – just days after terminating negotiations with another company, Kos, for a similar, if not better, sustained-release niacin product, Niaspan.[29] Why would Schering reject one sustained-release niacin product, and then a week later agree to make the largest up-front payment in its history for another sustained-release niacin product? At trial, Schering offered the testimony of Raymond Russo, Schering's

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payments. CPF 780-83.

[27] Tr. 18:4164 (Audibert); CX 1484 at 105 (Audibert dep).

[28] [redacted]; *see also* CPF 330-33.

[29] IDF 188 ("Niaspan and Niacor-SR were virtually identical"); CPF 735-63.

senior marketing director, to explain that Schering discontinued the Niaspan negotiations due to "factors not present in the Niacor license transaction." He identified a list of such factors, including Kos's demands for primary detailing of Niaspan, Kos's interest in booking Niaspan sales, and that Kos's people were "very difficult to work with." Schering Br. at 17.

The answer offered by Mr. Russo, however, is contradicted by Schering's contemporaneous documents. These documents demonstrate that Schering had fundamental concerns about the ability of a sustained-release niacin product to succeed in the marketplace. As Martin Driscoll, Schering's vice president of marketing (Mr. Russo's superior (Tr. 15:3483) (Russo)), explained in a memo dated eight days before Schering committed to pay Upsher $60 million: the "principal reason" for rejecting Niaspan was the product's limited market potential, which did not justify "distraction from [Schering's] core businesses." CX 558. According to Mr. Driscoll, Niaspan did not "represent a large-enough opportunity in the marketplace," and even this opportunity was "narrowing" prior to its introduction, because of the recent success of other cholesterol reducing agents. CX 558.[30]

Moreover, Schering understood from its review of Niaspan that a sustained-release version of niacin would have to "overcome some rather negative perceptions about niacin within the patient/medical community." CX 1047 at SP002747; *see also* CX 558 at SP002719. Schering commissioned a survey of ten medical experts to assess questions about Niaspan's

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[30] Other pharmaceutical firms were likewise concerned about the limited market potential of sustained-release niacin, and therefore rejected proffered licenses for Niacor-SR. *See, e.g.*, CX 850 ("[W]e do not expect that a product like Niacor can get a sufficient market share in Europe in the highly competitive segment of lipid lowering agents"); CX 857 ("We are doubtful about the commercial prospects of a nicotinic acid based product"); CX 861 ("The statins . . . are actually widely prescribed and there is not much room anymore for the nicotinic acids"); *see also* CPF 285, 586, 620-52.

negative side-effect profile, including its potential to cause liver damage. CX 576. These experts were unconvinced, based on available clinical data, that Kos had overcome the issues of "liver toxicity" and "side effects" that historically have plagued niacin products. CX 576 at SP020717-18. Nonetheless, Schering wants the Commission to believe that it disregarded the concerns of a senior executive and the warnings of its own expert medical panel about the potential difficulties of sustained-release niacin, which led to rejection of Niaspan just one week earlier, and paid an unprecedented $60 million for another sustained-release niacin product.

Niacor-SR, however, had not resolved the safety issues either. IDF 188 ("Niaspan and Niacor-SR were virtually identical"). At the time Schering agreed to this historic payment, Upsher had not even satisfied the FDA that Niacor-SR actually was what it purported to be – a sustained-release product.[31] Remarkably, Schering never asked to review Upsher's correspondence with the FDA, so it did not know that it was paying $60 million for a drug that might not receive approval as a sustained-release product – the principal feature that purportedly would give it commercial value.[32]

Taken as a whole, the record powerfully refutes respondents' claim, and the ALJ's finding, that the $60 million was entirely for Niacor-SR.

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[31] CX 1382 at Upsher-Smith FTC 107434 (Upsher did not "have adequate data to meet the regulatory requirements for an extended-release product"); CX 1383 at Upsher-Smith FTC 107457 ("approval of Niacor-SR as a controlled-release product [would be] dependent on the results" of a study submitted to the FDA).

[32] During Schering's one-man review of Niacor-SR, Mr. Audibert merely "assumed" that the product would receive the necessary regulatory approvals (Tr. 18:4130 (Audibert); Tr. 19:4384-85 (Lauda)); he never spoke with anyone at Upsher, requested any information from Upsher (Tr. 18:4168 (Audibert)), or contacted the principal personnel at Schering involved in the company's recent review of Niaspan. Tr. 18:4177-78 (Audibert).

B. Schering Paid AHP Not to Compete Until 2004

The Schering/AHP settlement agreement clearly shows that Schering paid AHP $15 million in consideration for AHP's promise to stay off the market until 2004. At paragraph 3.1(a)(iii):

> AHP and ESI each covenants that, in no event shall any or all of AHP, ESI, its or their Affiliates and/or any Acquired Businesses . . . prior to January 1, 2004, sell, offer to sell or market in the United States any Referencing Product [defined in Article I to include a potassium chloride product that is bioequivalent to K-Dur 20].

CX 479 at SP1300075. Schering, in return, at paragraph IV, agreed to pay AHP $5 million upon execution of the agreement, and up to $10 million more depending on the date that AHP's product received tentative FDA approval. CX 479 at SP1300078; *see also* CPF 880. AHP would get the full $10 million if it obtained FDA approval by June 1999, and lesser amounts if thereafter. *Id.* The agreement thus tied the size of the payment to AHP's potential losses (as well as Schering's gain) from AHP delaying its entry.

In a separate agreement, Schering also agreed to pay AHP a second $15 million, non-contingent payment for a license to the European marketing rights to two AHP products. CX 480. We did not offer evidence that any of this payment was for the 2004 entry date, because the first $15 million is sufficient to prove that Schering paid AHP for that date.

Evidence from the negotiations between Schering and AHP further confirms that Schering paid AHP not to compete until 2004: (1) AHP asked to be paid to stay off the market (CPF 857-59); (2) AHP held firm to that demand as a condition for agreeing to settle for an entry date several years into the future (CPF 858); and (3) the negotiations focused on calculating what AHP would lose by remaining off the market for several years (CPF 817-20, 862).

At trial, Schering did not seriously dispute that the settlement agreement shows that its $5 million unconditional payment, and the $10 million conditional payment, were in exchange for AHP's agreement to stay off the market until 2004. Instead, Schering witness Martin Driscoll tried to dismiss the $10 million conditional payment as "a bet" that he never expected to pay (as if this would make any difference). Moreover, Mr. Driscoll's testimony, which the ALJ credited, is belied by more reliable documentary evidence showing that the approvability of AHP's product was of "central importance" to Schering in agreeing to the conditional payment term. *See* CX 474 at SP1300633; *see also* CPF 866-68. Schering also offered testimony that it felt it was being forced by the trial judge presiding over the patent litigation to settle the case, but in its post-trial reply brief it disclaimed this as a defense.

Despite the clear and essentially uncontroverted evidence that Schering paid AHP $15 million for the 2004 entry date, the ALJ in his conclusions of law says that we failed to prove "that any payment was not for fair value" or "that the $15 million was paid *only* for unlawful delay." ID at 112 (emphasis added). Perhaps ALJ Chappell was confused by the fact that there were two $15 million payments from Schering to AHP, one of which was expressly in consideration for AHP's agreement to stay off the market until 2004. Moreover, the ALJ ignored much of the extensive documentary evidence regarding the negotiations, and, when he does refer to documents, he omits material information that bears directly on the anticompetitive purposes of the parties' agreement. For example, he repeatedly mentions Schering's co-promote proposal to AHP (IDF 335-36, 343, 346) without ever acknowledging that it required AHP to completely abandon its generic K-Dur 20 product (*see* CX 459; Tr 12:2662 (Hoffman)). This shows that, from the outset, Schering was willing to offer payment to eliminate any competition from AHP.

C. Conclusion

Based on the foregoing, and the totality of the record evidence, we ask the Commission to find that:

(i) Schering's $60 million payment to Upsher was, at least in substantial part, in exchange for Upsher's promise to stay off the market with its generic version of K-Dur 20 until September 2001.

(ii) Schering's $15 million settlement payment to AHP was in exchange for AHP's promise to stay off the market with its generic version of K-Dur 20 until January 2004.

In support of these findings, we ask to Commission to adopt, among others, complaint counsel's proposed findings of fact:

- relating to the Schering/Upsher agreement: CPF 176, 178-79, 181-82, 200-02, 204, 206-20, 225-28, 242-43, 245-46, 248-52, 288, 314-18, 417-19, 485-86, 722-26, 781-82, 798-802.

- relating to the Schering/AHP agreement: CPF 846, 872-75, and 879-81.

II. The Agreements Are Unlawful Horizontal Restraints

Schering's agreements with two companies seeking to market generic versions of K-Dur 20 are horizontal restraints and unlawful if they "unreasonably" limit competition.[33] To assess the reasonableness of a horizontal restraint, courts begin by asking whether the conduct appears to be a practice that would "always or almost always tend to restrict competition and decrease output," or instead is "designed to 'increase economic efficiency and render markets more, rather than less, competitive.'" *Broadcast Music, Inc. v. CBS*, 441 U.S. 1, 19-20 (1979) (*BMI*). When the nature of the restraint "gives rise to an intuitively obvious inference of anticompetitive effects," *California Dental Association v. FTC*, 526 U.S. 756, 781 (1999) (*CDA*), the burden shifts to respondent to provide evidence of a procompetitive justification. *National College Athletic Ass'n v. Bd. of Regents*, 468 U.S. 85, 113 (1984) (*NCAA*). The justification must be both sound in theory (plausible) and based in fact. *Mass. Bd. of Registration in Optometry*, 110 F.T.C. 549, 604 (1988) (*Mass. Board*). Absent such a justification, the restraint can be condemned without further inquiry.[34]

When the anticompetitive character of the restraint is less obvious or its justifications are sufficiently strong, one must inquire further to assess the restraint's likely competitive effects.[35] The scrutiny required to assess competitive effects under the rule of reason depends on the nature

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[33] *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 695 (1978).

[34] *NCAA*, 468 U.S. at 110.

[35] *NCAA*, 468 U.S. at 103-04.

and character of the restraint in question and the strength of its purported justification.[36] "What is required . . . is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint." *CDA*, 526 U.S. at 781. And this more lingering inquiry need not always include "a plenary market examination." *Id.* at 780.

Respondents' defense of their challenged agreements rests heavily on the premise that their legality turns on whether they are *per se* unlawful. The distinction is irrelevant because whether judged under a *per se* standard or a more extensive rule of reason examination, the evidence establishes a violation. Paying a potential competitor not to enter the market is presumptively anticompetitive. The record evidence establishes, moreover, that these agreements had anticompetitive effects by delaying generic entry beyond what was expected absent the payments. None of the purported justifications is both sound in theory and based in fact. Therefore, the Schering-Upsher and Schering-AHP agreements unreasonably restrain trade and are unlawful.

A. The Restraints Are Presumptively Anticompetitive

1. Paying a potential entrant not to enter is inherently anticompetitive

Some restraints are so plainly anticompetitive that, absent an efficiency justification, "no elaborate industry analysis is required to demonstrate [their] anticompetitive character." *Prof'l Eng'rs*, 435 U.S. at 692; *Mass. Bd.*, 110 F.T.C. at 604 (describing such restraints as inherently suspect). Fixing prices, allocating markets, and paying competitors to stay off the market are

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[36] *See, e.g.*, *NCAA*, 468 U.S. at 103-04; *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 461-62 (1986) (*IFD*).

presumptively anticompetitive.[37] "Restrictions on price and output are the paradigmatic examples of restraints of trade that the Sherman Act was intended to prohibit." *NCAA*, 468 U.S. at 107-08. As the Supreme Court made clear in *Palmer v. BRG of Georgia*, even when the firm's entry into the market is uncertain, paying a potential competitor to withhold competition is inherently anticompetitive. 498 U.S. at 49-50.

Schering's payments directly limited price and output competition. They delayed expected generic entry, enabling Schering to maintain high prices without losing sales. Schering paid Upsher not to enter until September 2001 and AHP not to enter until January 2004. Each agreement effectively is a temporal market allocation arrangement, under which Schering retains K-Dur 20 sales for several years and shares its profit with Upsher and AHP, which, in return, refrain from selling their competing generics. Accordingly, the agreements are presumptively anticompetitive.

2. The patent settlement context does not affect the conduct's presumptive anticompetitive character

While patent settlements can promote competition, they can also be vehicles for anticompetitive conduct. Thus, the Supreme Court has condemned agreements settling patent lawsuits as *per se* illegal.[38] In *United States v. Masonite*, for example, Masonite sued or threatened to sue its competitors for patent infringement. To resolve these disputes, Masonite

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[37] *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990) (per curium) (market allocation); *United States v. Socony Vacuum Oil Co.*, 310 U.S. 150, 218 (1940) (price-fixing); *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 301 (6th Cir. 1898) (Taft, J.) (payment not to compete), *aff'd*, 175 U.S. 211 (1899).

[38] *United States v. Singer Mfg. Co.*, 374 U.S. 174, 194-95 (1963); *United States v. New Wrinkle Inc.*, 342 U.S. 371, 378-80 (1952); *United States v. Line Material Co.*, 333 U.S. 287, 314-15 (1948); *United States v. Masonite Corp.*, 316 U.S. 265, 282 (1942).

licensed the competing firms to sell its product at a fixed price. 316 U.S. at 267-73. The Supreme Court expressly assumed that Masonite's patents were valid and that the competitors had tried unsuccessfully to develop non-infringing products. *Id.* at 276, 280-81. Nonetheless, the Court found that the licenses exceeded Masonite's legitimate rights and constituted illegal price-fixing. Masonite's licensing scheme enticed its competitors into abandoning their own products and patent challenges in exchange for a share of the patentee's profits. *Id.* at 281-83.[39]

Lower courts treat payments not to compete arising in patent litigation no differently from price-fixing agreements that are part of patent settlements. That is because, "with exceptions not relevant here, raising price, reducing output, and dividing markets have the same anticompetitive effects." *Gen. Leaseways, Inc. v. Nat'l Truck Leasing Ass'n*, 744 F.2d 588, 594-95 (7th Cir. 1984), *cited with approval, CDA*, 526 U.S. at 777. Two district courts found agreements similar to those challenged here – where potential generic entrants agreed to stay off the market for some period of time in exchange for money from the patent holder – to be *per se* illegal horizontal market allocation agreements. *Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, 701 (E.D. Mich. 2000) (*Cardizem*) (generic received at least $40 million annually for a promise not to enter before receiving a final judgment in the patent infringement case and not to relinquish its 180-day exclusivity), *appeal docketed*, No. 00-2483 (6th Cir. Dec. 19, 2000); *Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340, 1348-49 (S.D. Fla. 2000)

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[39] The Supreme Court has condemned other anticompetitive agreements involving an unresolved patent dispute, notwithstanding the possibility that the patent holder might have secured a court judgment excluding all competition for the life of the patent. *See supra* note 38.

(*Terazosin*) (two generic agreements under which each potential competitor received millions of dollars for promises not to enter market until a certain future event occurred), *appeal pending*.[40]

Schering's payments, like the price-fixing agreements settling patent disputes condemned in *Masonite*, provided "a powerful inducement to abandon competition." 316 U.S. at 281. By paying Upsher and AHP, Schering induced them to accept what the force of its patent alone would not – foregoing their patent challenges and staying off the market until the agreed-upon dates, several years into the future.

3. Patent rights do not eliminate the suspect nature of paying potential entrants not to enter

The ALJ apparently believed that Schering's patent gave it the right to pay Upsher and AHP not to enter the market until a judicial determination of patent invalidity or non-infringement. *See* ID at 99-101, 103-04. Neither antitrust law nor patent law supports this conclusion.

Antitrust law distinguishes between effects achieved unilaterally and those achieved concertedly. A patentee's proving infringement in litigation and its paying a potential entrant to withdraw its challenge are fundamentally different. What Schering might have been able to achieve unilaterally (by winning the patent suit) is no defense to Schering entering an agreement to pay its competitor not to compete. A price-fixing agreement is unlawful even if a party could have raised prices unilaterally. *Lee Moore Oil Co. v. Union Oil Co.*, 599 F.2d 1299, 1302 (4th

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[40] The ALJ distinguishes these cases by misstating the facts. ID at 97-98. Contrary to the ALJ's assertion, the agreement in *Cardizem* included a license that guaranteed the generic's ability to enter before patent expiration. 105 F. Supp. 2d at 696, 698. One of the arrangements in *Terazosin* was a final settlement. That court also rejected the contention that the agreements were procompetitive because they facilitated eventual generic entry. 164 F. Supp. 2d at 1350-54.

Cir. 1979) ("the fact that [the defendant] might have caused the same damages" by unilateral conduct is "irrelevant").

The ALJ's belief that the uncertain outcome of the patent litigation eliminates the suspect nature of Schering's payments directly contradicts *Masonite*. By the ALJ's reasoning, those agreements would not be presumptively anticompetitive because there was no evidence that Masonite's competitors would have been on the market. Masonite could, therefore, charge the same price that was fixed in the agreement. Moreover, the *Masonite* agreements provided more competition because they allowed Masonite's licensees to compete on nonprice terms. The Supreme Court, nonetheless, condemned the agreements on their face, despite the possibility that Masonite's patents could have blocked all entry. 316 U.S. at 282. The ALJ and respondents distinguish *Masonite* on the purported grounds that it involved price-fixing, but price fixing and payments not to compete "have the same anticompetitive effects." *Gen. Leaseways*, 744 F.2d at 592.

Patent law likewise does not support the ALJ's mistaken view that patent rights include the right to pay a competitor not to enter. "The heart of [the patentee's] legal monopoly is the right *to invoke the State's power* to prevent others from utilizing his discovery without his consent." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) (emphasis added), *rev'd on other grounds*, 401 U.S. 321 (1971). And, contrary to the ALJ's suggestion (ID at 103), the patent-holder must prove infringement, it is not assumed. By confusing the right to seek an injunction with the right to pay competitors to withdraw their patent challenges, the ALJ's ruling undermines the purpose of the patent system. A vital public interest exists in having invalid patents exposed as such through litigation. *See, e.g., United States v.*

Glaxo Group, Ltd., 410 U.S. 52, 58 (1973). Yet, if the patentee can pay to avoid a court determination, it is the weakest patents that will most likely trigger a payment.

The ALJ's ruling would effectively permit patent holders unbridled license to bribe their competitors not to compete. Under the ALJ's reasoning, the patentee could pay any amount of money in exchange for any split in the patent term (so long as the generic did not agree to stay out of the market for *longer* than the term of the patent), without antitrust liability. For while the ALJ would require that complaint counsel show that Upsher and AHP would have won in order to show anticompetitive effects, he concedes that such an undertaking is impossible. ID at 104.

Over a hundred years ago, Judge (later Chief Justice) Taft analyzed an agreement where competitors agreed not to bid on certain products, and the winner then passed along a share of its profits to the non-bidder. *Addyston Pipe*, 85 F. at 294-95. Judge Taft asked rhetorically, "Can there be any doubt that this was a restraint of interstate trade and commerce?" *Id.* at 295. Here, Schering's patent provides no reason to alter the conclusion that Schering's payments to Upsher and AHP to refrain from competing raise an obvious inference of anticompetitive harm.

B. A More Extensive Rule of Reason Inquiry Confirms That the Agreements Are Anticompetitive

A more detailed inquiry into the competitive effects of the agreements confirms their anticompetitive character. Generic K-Dur 20's entry would offer consumers a lower-priced alternative. Delaying that entry, therefore, harmed consumers. The record shows that the market structure here created incentives to delay generic entry and that the parties' actions were consistent with those incentives. Schering's payments to Upsher and AHP secured later entry dates and less competition than was expected in the absence of the payments. Under the rule of

reason, such a reduction in uncertain competition is an anticompetitive effect. The Upsher settlement had additional anticompetitive effects as well, because it delayed the triggering of Upsher's 180-day exclusivity period. Both agreements, moreover, prevented Upsher and AHP from developing non-infringing products – further exacerbating the harm.

1. Upsher and AHP represented potential competition that would have benefitted consumers

The first issue in determining the agreements' anticompetitive effects is whether Upsher's and AHP's entry would benefit consumers. To answer that question, the Commission must determine how a generic version of K-Dur 20 would affect the brand's sales and price, and, in the absence of [redacted]c version of K-Dur 20, how other branded and generic potassium supplements affected the sales and price of K-Dur 20.

Abundant record evidence shows that Schering enjoyed substantial market power over K-Dur 20 prior to generic entry. The ALJ's decision, to the contrary, rests on his misunderstanding of the nature of the inquiry. For example, he credits unsubstantiated testimony over documents. He relies on how many different potassium chloride products are reported by IMS (a data collection corporation), instead of looking at what that market data show about the sales and prices of those products. And he relies on evidence that Upsher tried to promote its 10 mEq product as a substitute for K-Dur 20, instead of the evidence that Upsher's attempt failed dismally. Virtually none of his market findings addresses the key questions, and none addresses the simple market facts that: (1) generic K-Dur 20 was predicted to take substantial sales from branded K-Dur 20 at a substantial discount; (2) other generic potassium supplements, even new entrants, had little impact on K-Dur 20's sales, profits, or prices (although they affected the sales

of other branded potassium supplements); and (3) actual entry by generic K-Dur 20 had the predicted effects.

a. Market participants expected generic K-Dur 20 to have a unique competitive impact

Prior to entering the agreements challenged here, Schering, Upsher, and [redacted] consistently predicted that generic K-Dur 20 would have a significant adverse impact on branded K-Dur 20's sales and the market price of 20 mEq potassium chloride. CPF 83-84, 96-97, [redacted], 956-57, 962, 964-67, [redacted] Their forecasts show that the generic would enter at a substantially discounted price and cause K-Dur 20's sales and profits to fall, providing substantial savings to consumers:

- c K-Dur 20 – including Schering's own generic version – was expected to be priced 50% below branded K-Dur 20.[41]
- Generic K-Dur 20 was expected to take from 30% to 50% of branded K-Dur 20's sales within months of entry.[42]
- [redacted]

All of the projections show branded K-Dur 20's unit sales or dollar sales decreasing after generic entry. Tr. 3:462-63 (Bresnahan).

In addition, Schering planned to offer its own generic K-Dur 20, through its Warrick subsidiary, at a 50% discount off branded K-Dur 20's price, but only in response to the entry of

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[41] *See, e.g.,* CX 150 at USL08535 (Upsher's product would be priced, on average, at 50% of K-Dur); [redacted]; *see also* Tr. 3:461 (Bresnahan) (showing that AHP "thought that there would be substantial impact from generic entry.").

[42] *See, e.g.,* CX 133 at SP 2500004 (showing generic entry taking almost half of K-Dur 20's sales within four months of entry); CX 18 at SP2300044 (Schering "1997 K-Dur Marketing Plan" stating that: "Although generic entry is not likely until 1998 the impact of a generic 20 mEq product would be significant").

an independent generic K-Dur 20 product.[43] CPF 1115. Schering thus planned to lower its average price in response to generic K-Dur 20 entry. Tr. 3:439-40 (Bresnahan).

As the forecasts show, Schering, Upsher, and AHP recognized that Schering, prior to generic K-Dur 20 entry, had the power to keep the price of K-Dur 20 high without losing sales. Tr 3:430 (Bresnahan). Additionally, the forecasts show that Schering, Upsher, and AHP were each aware of the dramatic negative impact that generic K-Dur 20's entry was expected to have on Schering's K-Dur 20.

Respondents' forecasts are consistent with the empirical literature analyzing the effects of generic entry.[44] A generic drug enters the market at a price well below its branded counterpart, with the first generic entrant coming in at a price, on average, 25% lower than the brand's price.[45] Each subsequent generic entrant causes prices to fall more.[46] These same studies document the rapid erosion of a branded drug's sales once a generic version is introduced.[47]

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[43] *See, e.g.,* CX 133 at SP2500004 (Schering "1997 Operating Plan").

[44] *See, e.g.*, Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J. L. & Econ. 331 (Oct. 1992); Richard E. Caves, et al., *Patent Expiration, Entry and Competition in the U.S. Pharmaceutical Industry*, *in* Brookings Papers on Economic Activity (1991).

[45] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* xiii (1998).

[46] Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. Econ. & Mgmt. Strategy 75, 88 (Spring 1997).

[47] Henry G. Grabowski & John M. Vernon, *Longer Patents for Increased Generic Competition in the U.S.*, PharmacoEconomics (1996) (brand lost 50% of prescriptions within a year of AB rated generic entry); *see also* CBO, *supra* note 45 (AB-rated generics captured roughly 44% prescriptions dispensed by pharmacies for the brand).

The empirical literature and respondents' own forecasts show that when generic products like generic K-Dur 20 are able to enter the market, a substantial segment of consumers will avail themselves of the lower-priced generic products, thereby realizing significant cost-savings. If, however, generic entry is delayed, consumers lose the opportunity to reap the substantial benefits of lower-priced generics.

b. Other potassium chloride supplements did not constrain K-Dur 20's sales, prices, or profit

As Professor Bresnahan explained, 8 and 10 mEq potassium supplements (the only other tablets or capsules) provided very little constraint on K-Dur 20. Tr. 3:476 (Bresnahan). No evidence indicates that 8 and 10 mEq products were causing Schering to lower its price or lose sales. Tr. 3:483 (Bresnahan):

- The 1996 entry of generic 8 and 10 mEq potassium chloride products had *no* impact on K-Dur 20, but had a significant impact on other 8 and 10 mEq products; and
- Since its September 2001 entry, lower-priced generic K-Dur 20 has taken more than half the sales of branded K-Dur 20.

1) 1996 entry of generic 8 and 10 mEq potassium chloride products

In 1996, Apothecon, AHP, Medeva, and Biocraft all began selling generic versions of branded 8 and 10 mEq potassium supplements. IDF 406. Their entry had virtually no impact on K-Dur 20. As depicted in Figure 6, Schering's K-Dur 20 prescriptions increased continually from 1994 until generic K-Dur 20's entry, when branded K-Dur 20's sales declined dramatically.

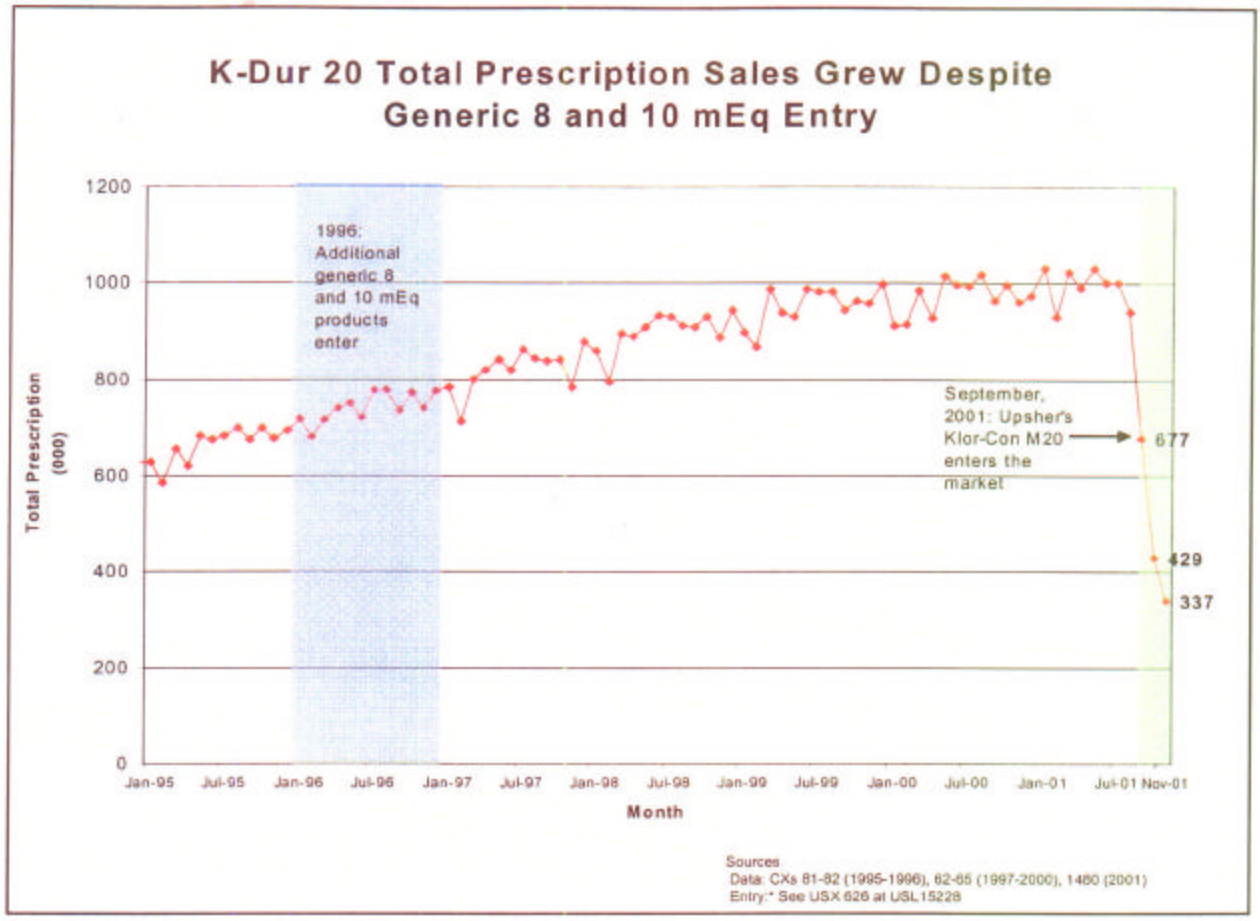

Figure 6

Moreover, throughout this period, the number of K-Dur 20 prescriptions increased at a faster rate than the entire class of potassium supplements.[48] CPF 976.

The ALJ largely ignored this data and found that "significant substitution" for K-Dur 20 was occurring – relying on Upsher witness Phillip Dristas's assent to his attorney's leading question, and on hearsay testimony not admitted for its truth. IDF 59. In fact, industry data show that doctors were not switching prescriptions to other potassium products, nor were pharmacists.

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[48] Tr. 3:476 (Bresnahan). *See also* CX 18 at SP 2300040 ("K-DUR sales continue to increase, up 20% from the previous year").

The number of prescriptions written for K-Dur 20 increased faster than the growth for all potassium chloride supplements.[49] At the pharmacy level, 99.9% of all K-Dur 20 prescriptions were filled as written.[50]

Schering's increased its sales and price, despite entry of non-AB-rated potassium supplements. From 1996 until generic K-Dur 20 entry, K-Dur 20 "commanded a substantial price premium over . . . the then existing generics."[51] Nevertheless, Schering profitably raised its own invoice price continually, without losing substantial sales. *See* Figure 1. And, as measured by IMS Health data, Schering increased price relative to generic 8 and 10 mEq tablets and capsules (the only other group of potassium supplements with substantial growth). *See* Table 1; *see also* CPF 973, 975, Tr. 20:4843 (Dritsas).

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[49] CX 43 (comparing % category at SP020658 (33% in 1996), SP020664 (35% in 1997), SP020670 (37% in 1998), SP020676 (38% in 1999).

[50] CPF 1001-02, 1117.

[51] Tr. 3:475 (Bresnahan). *See also* CX 18 at SP2300039 ("1997 K-Dur Marketing Plan," Sep. 10, 1996, K-Dur market manager comparing price of generic 8 and 10 mEq to K-Dur 20 and finding a "30% price advantage" over branded K-Dur 20).

Table 1 K-Dur 20's Price Premium Over Generic 8 and 10 mEq Products, 1995-1999[52]					
	K-Dur 20's Price Premium (in cents per 20 mEq dose)				
Generic Product	1995 (K-Dur 20=$0.31)	1996 ($0.34)	1997 ($0.36)	1998 ($0.42)	1999 ($0.44)
Klor-Con 8mEq	+.16	+.19	+.21	+.24	+.27
Klor-Con 10 mEq	+.15	+.20	+.22	+.27	+.29
Qualitest 10 mEq	+.20	+.24	+.28	+.36	+.36
Apothecon 10 mEq	n/a	+.09	+.24	+.31	+.34
Copley 8 mEq	+.15	+.19	+.27	+.31	+.32
AHP 10 mEq	-.04	+.22	+.27	+.32	+.36
Ethex 10 mEq	+.15	+.20	+.22	+.28	+.22
Warner-Chilcott 8 mEq	+.25	+.29	+.30	+.31	+.34
Warner-Chilcott 10 mEq	+.14	+.18	+.21	+.32	+.37
Alra 10 mEq	.+22	+.27	+.29	+.35	+.41

The only exception, Ethex's generic, confirms the unique dynamic between a generic and its branded counterpart. Between 1998 and 1999, the price difference between the Ethex 10 mEq generic and K-Dur 20 did decline, but only because Ethex bought the branded version of its generic product and then raised prices on both the brand and generic without losing sales. CPF

[52] These are average prices based on total extended units (tablets) (CX 41) and total dollars (CX 40) as measured by IMS. The list includes all generic 8 or 10 mEq companies that had at least sales of 10,000 units (unit = one 20 mEq dose) per year.

1125-28. Throughout this same period, Schering's K-Dur 20's net sales and profits increased. *See* Figure 2.

K-Dur 20's experience starkly contrasts to the impact of entry by generic 8 and 10 mEq products on other branded potassium chloride products. Every branded 8 and 10 mEq potassium product lost substantial sales. CPF 975. As figure 7 shows, total prescriptions for potassium supplement tablets (excluding K-Dur 20 and K-Dur 10) remained constant. Generic 8 and 10 mEq products gained sales, not at the expense of K-Dur 20, but at the expense of branded 8 and 10 mEq products.

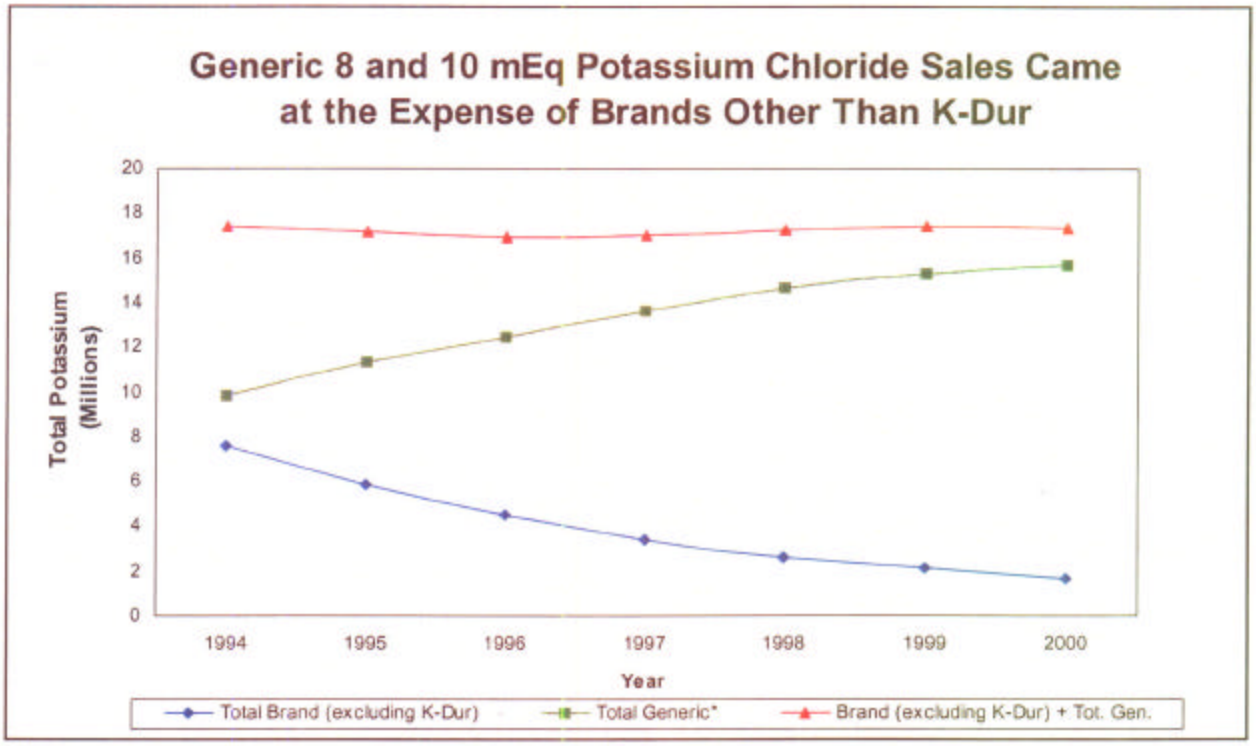

Figure 7

Schering enjoyed substantial pricing power over K-Dur 20 prior to generic entry, and thus Schering had substantial market power.

2) 2001 entry of generic K-Dur 20

Sales data from the first few months after generic K-Dur 20's entry show that generic K-Dur 20 had the effect forecasted by Schering, Upsher, and AHP. Generic K-Dur 20 was priced at a substantial discount from the brand (CPF 990), and consumers switched in large numbers from K-Dur 20 to its generic version. CPF 988-92. Within three months of Upsher's entry, "more prescriptions [were] dispensed for the generics than for the brands." Tr. 3:473 (Bresnahan); CPF 989; *see* Figure 5. And, as planned, Schering launched its own generic K-Dur 20 product in response to Upsher's entry. CPF 989-92, 1114. Generic entry dissipated the market power Schering enjoyed prior to generic entry. Tr. 3:472-73 (Bresnahan).

2. The market structure created incentives to delay entry

The market structure in which generic K-Dur 20 entry would occur provides the context in which to assess the likely effects of the challenged agreements. The economic incentives that the market structure creates can shed light on the purpose and likely effects of the settlement agreements. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 596-97 (1986). The ALJ failed to understand the role of incentives in assessing the effect of the agreements (as opposed to inferring the existence of an agreement (ID at 110)) and dismissed the evidence that the respondents' actions were consistent with their incentives.

The market structure in which the agreements arose created an incentive for the parties to delay entry. Generic entry would harm Schering more than it would benefit the entrants because,

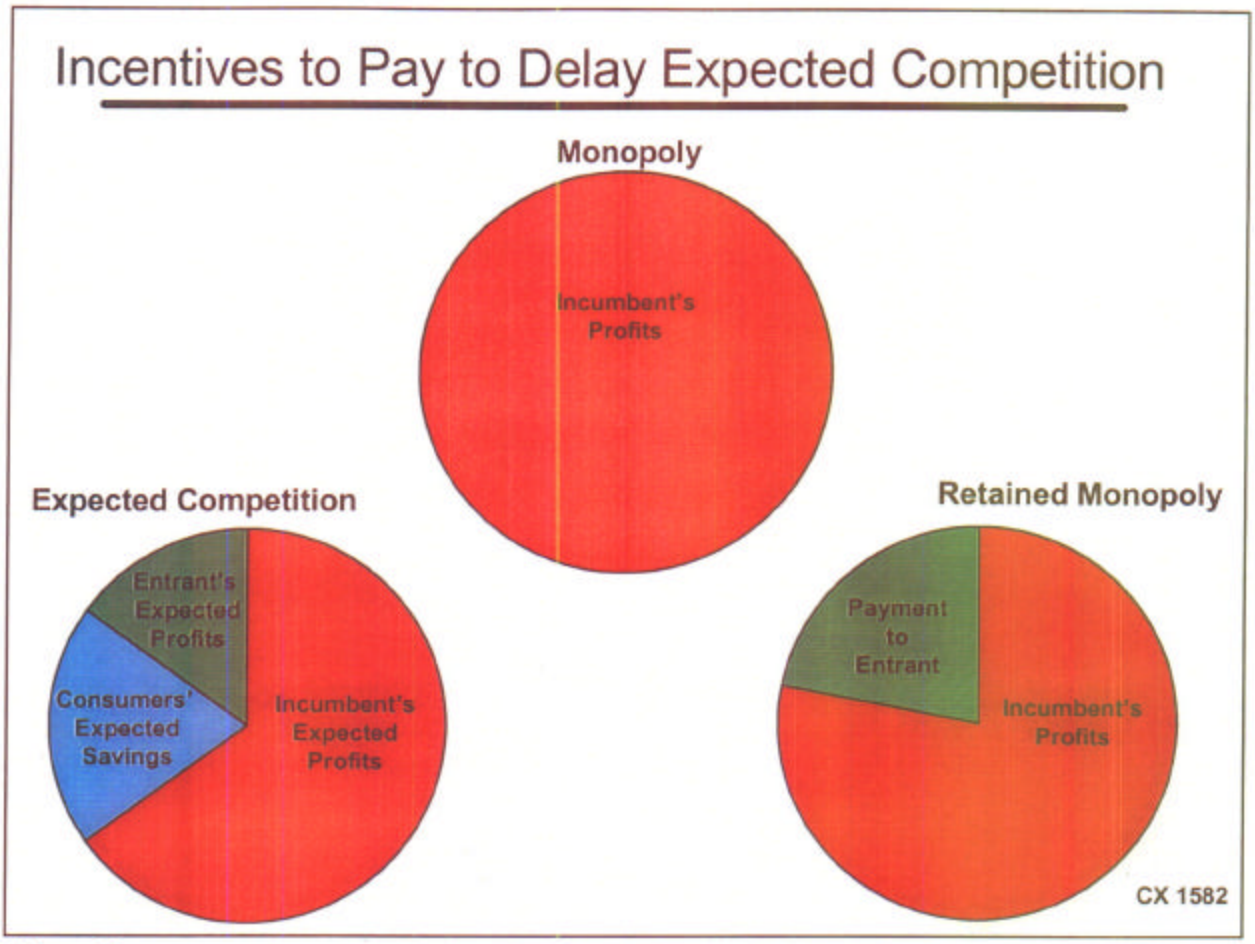

Figure 8

due to the brand-generic price disparity, Schering would lose more in profits than the entrants would gain. CPF 1151, 1155. Schering could pay Upsher and AHP more than either would earn, therefore, and still be better off than if it faced competition. CPF 1154-56. Even with entry uncertain, the same incentives exist, as the accompanying diagram shows: with entry uncertain, Schering would pay only as much as it expects to lose (based on the probability of entry occurring), and the entrant would require only as much as it expects to earn. CPF 1162-64. Under these market conditions, the brand firm and its generic rival are always better off by eliminating their expected competition and sharing the brand's monopoly. CPF 1165.

Not only did financial incentives exist to delay entry (CPF 1173-77), but they were large. Generic entry would cost Schering $7 million per month while Upsher and AHP would have profited by only $1-1.25 million per month. CPF 1178-82. The longer Schering could delay generic entry, the longer it could continue to maintain its K-Dur 20 revenues.[53] The agreements enabled Schering to charge monopoly prices to consumers, compensate Upsher and AHP for their expected lost profits, and still earn more than it expected absent the agreements' payment provisions. Schering funded its payouts to Upsher and AHP with money from consumers, who continued to pay high prices. CPF 1184.

As Professor Bresnahan explained, respondents discussed and made the profit-maximizing payment calculations during settlement negotiations.[54] The issues on which they focused demonstrate the anticompetitive character of the settlements: Schering's willingness to pay Upsher only as long as Upsher was a unique threat; Upsher's and AHP's demand for money to replace lost revenues; and Schering's calculation of those lost profits. CPF 1194-98, 1215. Schering's paying Upsher its lost profits, and tying the amount of the AHP payment to AHP's regulatory approval, further demonstrate that the payments were for delayed entry. CPF 1188-90, 1200, 1211-12.

3. Schering's payments to Upsher and AHP delayed generic entry beyond what the parties expected absent the payments

Simply as a matter of common sense, Schering would not pay Upsher and AHP millions of dollars, unless it obtained something in return. In the context of negotiations about when

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[53] CPF 1176, 1181; *see also* CX 13 (Schering strategy to "[m]aximize length of time to introduction" of generic competition to K-Dur 20).

[54] CPF 1182, 1188, 1193, 1199.

generic entry will be allowed, the obvious trade-off for the money is later entry. Courts that have addressed brand-firm payments to alleged generic infringers in settlement of litigation have repeatedly observed that such payments bought delayed generic competition and are anticompetitive.[55] For example, in *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001), the D.C. Circuit held that it was proper to infer that a substantial payment made to a potential generic entrant in exchange for a mutually agreed entry date was likely to delay entry. *Id.* at 809. The court of appeals noted that the brand firm's ten million dollar quarterly payments were presumably in return for something that the generic would not otherwise do, that is, delay marketing of its competing product. *Id.* at 813.

Basic economic principles reinforce this common-sense intuition. Patent litigants evaluating settlements will balance the expected gains from litigating against the certain gains from settling. They will settle only if settlement terms provide as much profit as each party expects to earn if the litigation proceeded to conclusion. The generic firm compares the income it will earn from the agreed entry date with its expected income after litigation (which it bases on the profit from entry, the likelihood that it will win the lawsuit, and the cost of litigation). Absent a payment, the entrant will accept a settlement that provides it with at least as much

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[55] *See, e.g., Terazosin Antitrust Litig.*, 164 F. Supp. 2d at 1351 ("[T]he suggestion that Abbott handsomely paid Geneva to spur competition in its own lucrative domestic market for terazosin hydrochloride is patently unreasonable."); *Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d at 699 (agreement is *per se* unlawful market allocation); *Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 2d 740, 750 (E.D.N.Y. 2001) (acknowledging logic in allegation that payment was for delay in generic entry and payor intended to share monopoly returns on the drug); *Biovail Corp. Int'l. v. Hoechst A.G.*, 49 F. Supp. 2d 750, 766 (D.N.J. 1999) (a reasonable trier of fact could conclude that agreement between two competitors to delay running of the Hatch-Waxman exclusivity period to keep another competitor out of the market is an unreasonable restraint of trade).

income as it expects to earn through litigation. The brand will make a similar calculation and accept an entry date that provides as little competition as it expected to occur through litigation. A settlement that does not pay money to the generic, therefore, reflects the parties' best assessment of the competition likely to result after a judgment (the "expected entry date under litigation").

Drawing an inference of delayed entry from Schering's payment does not, as the ALJ wrongly concluded, require making any assumptions about who would have won the litigation (ID at 4), or when entry would have occurred but for the settlement. ID at 104-05. Instead, economic theory teaches that if the parties engage in arm's length bargaining, their settlement will reflect their contemporaneous expectations about the litigation results. *See* Tr. 4:610 (Bresnahan). Absent a payment, the parties' interests in negotiating a settlement directly conflict: Schering wanted the latest entry date possible to preserve its K-Dur 20 profits; Upsher and AHP wanted the earliest entry date possible. CPF 1151.

But, if the potential entrant is offered both an entry date and a share of the incumbent's profits, the interests of the parties align, for together they can delay entry and share the increased profits. CPF 1161-65; *see also* CPF 1150-58. The incumbent is willing to pay for an entry date only if it provides less competition (and more profit) than it expects to earn under litigation; the incumbent, accordingly, will pay only if the settlement date is later than the entry date that the brand expects to occur under litigation. CPF 1219. Likewise, when the generic requires a payment to accept an entry date offered by the brand – as Upsher and AHP did – that entry date provides less competition than the entrant expects under litigation. CPF 1220-21.

Respondents' experts went to great lengths to defy these basic economic principles by spinning complicated scenarios under which it might be possible that a payment would not lead to a later date than is expected under litigation. These efforts failed, however, both as a matter of proof and as a matter of theory. Most fundamentally, none of the scenarios is present in this case. Moreover, the scenarios actually confirm the anticompetitive effect of the settlements. CPF 1248. For under any of the scenarios, it would be economically irrational for the parties not to delay the generic's entry. *See infra*, Section III.C.4; CPF 1228.

The Commission should conclude:

- Because Schering was willing to pay Upsher $60 million for the September 2001 entry date (and AHP for the 200[illegible] these dates were later than its assessment of the expected entry date under litigation.
- Because Upsher required a payment to accept the September 2001 date (and AHP required payment for the 2004 date), these dates were later than their assessments of the expected entry date under litigation.
- Had they settled without a payment, entry would have occurred earlier.
- The payments, therefore, delayed generic entry.

4. Delaying generic entry by Upsher and AHP is anticompetitive, even though their entry was uncertain

Having shown that generic K-Dur 20 competition benefits consumers, and that Schering's payments delayed such competition, the remaining question is whether the reduction in competition from parties whose entry was uncertain is an anticompetive effect. The ALJ was fundamentally mistaken in accepting respondents' argument that no anticompetitive effects were proven because we had not shown when Upsher or AHP would otherwise have entered the market. ID at 102-05. As a matter of economics, agreements to delay uncertain competition

clearly are anticompetitive and harm consumers. And, as a matter of law, no proof of what would have happened but for the challenged restraint is needed.

Delaying potential competition harms consumers in exactly the same way that destroying existing competition does, though discounted by the probability of entry. Consumers are always better off with the possibility of competitive entry and lower prices than they are with either the certainty of no entry or some guaranteed lesser amount of competition. *See* CPF 1166-72. Reflecting this economic reality, the courts have long recognized that agreements to delay uncertain competition have anticompetitive effects. Since *Chicago Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918), the rule of reason inquiry has focused on the restraint's "effect, actual or probable." As the leading antitrust treatise explains, "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." XII Herbert Hovenkamp, *Antitrust Law* ¶ 2030b at 175 (1999).[23] Uncertainty about the time of entry may influence a plaintiff's ability to prove damages but does not alter the analysis of liability.[24]

Applying the rule of reason under Section 2 of the Sherman Act, the D.C. Circuit in *United States v. Microsoft Corp.* confirmed that impeding "nascent" rather than actual

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[23] It clearly would be anticompetitive for an incumbent to pay a potential generic rival to defer entry until a specific date in the future, even if the generic's ability to obtain FDA approval was uncertain. From an economic point of view, there would be no reason to treat uncertainty due to patent litigation any differently. *See* Tr. 34:8085-87 (Bresnahan).

[24] *See, e.g., United States v. Microsoft Corp.*, 253 F.3d 34, 79-80 (D.C. Cir. 2001) (per curiam) (distinguishing liability and remedy); *Andrx v. Biovail,* 256 F.3d at 806, 808 (holding plaintiff need establish only threat of injury to have standing for injunctive relief); *Microbix Biosys., Inc. v. BioWhittaker, Inc.*, 172 F. Supp. 2d 680, 694-95 (D. Md. 2000) (distinguishing damages inquiry from assessment of competitive effects for purposes of assessing liability under rule of reason), *aff'd on other grounds,* 2001 WL 603416 (4th Cir. June 4, 2001).

competition is a fully cognizable anticompetitive effect. 253 F.3d 34 (D.C. Cir. 2001) (per curium). Rejecting Microsoft's argument that the government did not establish a causal link between Microsoft's foreclosure of Netscape's and Java's distribution channels and the maintenance of Microsoft's monopoly, the court – in an action for injunctive relief – held that it could infer causation even when the exclusionary conduct is aimed at nascent competitive technologies. "Admittedly, in the former case there is added uncertainty, inasmuch as nascent threats are merely *potential* substitutes. But the underlying proof problem is the same – neither plaintiffs nor the court can confidently reconstruct a product's hypothetical technological development in a world absent the defendant's exclusionary conduct." *Id.* at 79 (emphasis in original). It was not the government's burden to establish a "but for" world – to show that Java or Netscape would have become viable substitutes for Microsoft's operating system. Rather, the central question was whether "as a general matter the exclusion of nascent threats is the type of conduct that is reasonably capable of contributing significantly to a defendant's continued monopoly power" and whether the potential entrants constituted nascent threats at the time the conduct was undertaken. *Id.* As the court recognized, "it would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will . . . ." *Id.*

Here, just as in *Microsoft*, the potential entrants clearly constituted threats to the incumbent. Each company was seeking immediate approval to sell generic K-Dur 20 (CPF 85-97, 809-20, 841-45), and each had a substantial possibility of prevailing in the patent litigation.

CPF 98-117, 821-40.[25] Indeed, Schering plainly thought that entry by Upsher before 2001 was sufficiently likely that it paid millions of dollars to protect against that possibility, which according to Schering itself, gave K-Dur 20 sales "a new lease on life." CX 20 at SP004040. Upsher's conduct and statements prior to the agreement also show it believed it was likely to launch its product well before 2001; [redacted] CPF 118-62 ([redacted]). Likewise, Schering satisfied itself that AHP's product was likely to obtain FDA approval before agreeing to pay at least $15 million for its agreement not to enter until 2004.

Because the reduction in uncertain competition itself is an anticompetitive effect, proving what would have happened absent the restraint is not an element of an antitrust action. *IFD*, 476 U.S. at 461-62 (condemning agreement among dentists to withhold x-rays from insurers without proof that the restraint "resulted in higher prices . . . than would occur in [the conduct's] absence"). Even if subsequent events meant the likely effects of the agreement would not have materialized – for example, because Upsher's plant had burned down, it failed to obtain necessary regulatory approvals, or for some other reason – that would not alter the conclusion that when the agreement was entered into, it was likely to cause substantial competitive harm.[26]

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[25] *See also* Complaint Counsel's Reply to Schering-Plough's Proposed Findings Relating to the Underlying Patent Cases and the appendix to complaint counsel's reply brief for a full discussion of the patent issues (Apr. 26, 2002).

[26] *Microbix*, 172 F. Supp. 2d at 694-95 (an exclusive supply agreement that created a barrier to competition at the time it was entered into could be condemned under the rule of reason, even though subsequent action by the FDA made it impossible for the target of the exclusionary conduct to enter the market); *Terazosin*, 164 F. Supp. 2d at 1351-52 (agreement to delay entry illegal even if the generic could not be brought to market for other reasons).

Similarly, uncertainty about whether Upsher and AHP ultimately would have prevailed in the patent cases does not undermine the likely anticompetitive effects of the agreements.

There is no basis, consequently, for the ALJ's and respondents' assertions that the agreements were not anticompetitive because other factors might have prevented entry in any event. Just as Microsoft's exclusionary conduct provided less competition in an expected sense, so too did the settlements at issue. Given the obvious effect that large payments to stay off the market have on a generic firm's decision about when to enter, the challenged agreements here are "likely enough to disrupt the proper functioning of the price-setting mechanism of the market" that they may be deemed anticompetitive even without proof that they actually "resulted in higher prices. . . than would occur in [the conduct's] absence." *IBM*, 476 U.S. at 461-62. Indeed, as the D.C. Circuit observed in *Microsoft*, to rest antitrust liability on a requirement that plaintiffs "reconstruct the hypothetical marketplace" absent the challenged conduct would merely encourage "more and earlier anticompetitive action." 253 F.3d at 79.

5. The Schering/Upsher agreement created additional anticompetitive effects by erecting a barrier to entry by other generics

The Schering/Upsher agreement not only delayed entry by Upsher, but also created an obstacle to entry by other generic competitors. *See* CPF 926, 928-29. That is because the delay in Upsher's market entry that Schering bought with its multi-million payment also delayed Upsher's triggering of its exclusivity period. In this respect, the agreement can be seen as a way of purchasing insurance against entry by other generic competitors.[27] The complaint does not

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[27] There might still have been some possibility that another applicant could trigger Upsher's exclusivity by obtaining a favorable court decision in a patent challenge brought by Schering (CPF 921-22), but Schering could avoid this possibility by not suing the ANDA filer for infringement. *See* CPF 929.

charge that this additional effect created an independent violation or allege a separate conspiracy concerning the exclusivity period. Rather, the impact on third parties is merely another anticompetitive effect of the agreement to exchange payments for delayed generic entry. The ALJ's conclusion (IDF 395-98; ID at 114) that this barrier did not have anticompetitive effects – because the exclusivity period did not actually block any firm that was otherwise in a position to go to market – is plainly incorrect. The parties' agreement delayed the elimination of a barrier to generic entry. That outside events created additional obstacles to that entry does not undermine the anticompetitive tendency of the agreement.

6. The collateral restraints are further evidence of the anticompetitive character of the agreements

The ALJ's holding that the agreements' ban on competing with *any* 20 mEq micro-encapsulated potassium chloride product is merely a lawful ancillary restraint cannot be sustained. IDF 167-68, 376-77 and ID 112-13; *see* CPF 1224-26. Whatever their justification might be in settlements that do not involve a payment for delay, the provisions in these agreements were not ancillary to an efficiency-enhancing arrangement. On the contrary, the requirements reinforced anticompetitive arrangements to keep Upsher and AHP from undertaking any generic competition to K-Dur 20 for several years. This was part of the package of restraints that Schering bought with its multi-million dollar payments.

Morever, the Schering/AHP agreement includes other restraints that bar AHP from conducting bioequivalence studies, selling more than one generic product between 2004 and 2006, and transferring its ANDA. CPF 881. These restrictions go far beyond anything that was arguably reasonably necessary to settle the lawsuit and are further evidence that the agreement

was designed to delay any generic entry. While the ALJ acknowledged the existence of these additional restrictions (IDF 376), he dismissed their significance, asserting that these provisions merely prevented AHP from making "insubstantial" modifications to the product and filing another ANDA for an infringing product. IDF 377. In fact, these restrictions plainly go far beyond preventing AHP from making minor modifications and instead bar it from undertaking any efforts to develop a competing generic K-Dur 20, no matter how different it might be from its original ANDA product.

C. Because The Purported Justifications for the Payments Fail, the Agreements Are Unlawful

Given the anticompetitive nature and effects of the settl[illegible]reements, they can be condemned unless they have a plausible countervailing procompetitive justification with some basis in fact. *NCAA*, 468 U.S. at 103, 113-14; *Mass. Bd.*, 110 F.T.C. at 604. The burden rests with respondents to come forward with evidence of procompetitive justifications. *NCAA*, 468 U.S. at 113. Respondents must, therefore, show that paying the potential entrants not to compete was reasonably necessary to promote competition. *NCAA*, 468 U.S. at 110.

To be a plausible justification, the restraint's purpose must be to enhance competition (*see, e.g., id.*, at 116-117), the restraint must be likely to achieve significant efficiencies (*BMI*, 441 U.S. at 19-20), and the restraint must actually further the purposes for which it is offered. *Gen. Leaseways,* 744 F.2d at 595. A justification is not cognizable when it rests on the premise that competition itself is causing the problem (*Prof'l Eng'rs*, 435 U.S. at 696), when it will provide little benefit or will logically lead to anticompetitive results (*BMI*, 441 U.S. at 19-20), or

where it does not further the purported justification. *Law v. NCAA*, 134 F.3d 1010, 1022 (10th Cir. 1998).

In addition, a justification must have some basis in fact; that is, there must be actual record evidence sufficient to conclude that the restraint serves a legitimate purpose. Thus, a justification is invalid if it is pretextual, if its benefits are speculative in the given context, if the benefits do not occur, or if the restraint is not reasonably necessary to achieve the result. *NCAA*, 468 U.S. at 114.

Respondents' purported justifications for Schering's payments to Upsher and AHP all fail, because they are unsupported by the facts, theoretically flawed, or both.

1. The Niacor-SR license is not a justification for Schering's payment to Upsher

Respondents' argument that the entire $60 million payment from Schering to Upsher was for the Niacor-SR license is contradicted by abundant record evidence that establishes that at least a substantial portion of this payment was consideration for Upsher's agreement not to market its product until September 2001. *See supra* Section II.A. This justification, therefore, should be rejected.

2. Settling litigation is not a justification for paying a potential entrant not to compete

Respondents suggest that the payments were necessary to resolve the litigation.[28] This, however, cannot be a plausible justification. Rather than creating synergies or efficiencies, the settlement was made possible through the transfer of expected consumer savings to Schering,

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[28] If bundling the payment for Niacor-SR with the settlement was necessary to settle the litigation, then logically some portion of the payment was for the entry date, and not Niacor-SR.

Upsher, and AHP.[29] Schering was willing and able to pay because it earned more from the absence of competition than Upsher or AHP gained from entry. The difference between Schering's loss and the entrants' gains was the expected consumer savings. Tr. 3:427-28 (Bresnahan). By depriving consumers of the expected savings from generic entry, Schering and its potential competitors were able to resolve their differences.

Preventing Schering and its potential competitors from settling on such terms would not prevent them from using any number of other methods of reaching settlement. For example, Upsher could have paid for the right to enter by taking an immediate license, in which case it would have been buying the right to compete instead of being paid not to compete, or the parties could have split the patent life without a payment. But the parties were not free to arrogate consumer benefits to themselves in order to resolve their differences, regardless of the form of their agreement not to compete.

3. Guaranteeing some competition is not a justification for the settlements

Respondents also argue that the settlement guaranteed generic competition before patent expiration. This argument is not a cognizable justification, however, because it rests on the premise that competitors are entitled to determine through private agreement the correct amount of competition in the marketplace. Competition should set prices and output. *Cf. Chi. Prof'l Sports Ltd. v. NBA*, 961 F.2d 667, 674 (7th Cir. 1992). Indeed, arguing that paying Upsher and AHP not to enter the market provides as much competition as consumers deserve is akin to cartel

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[29] In the field of negotiations, reaching an agreement by taking value from parties not involved in the negotiations is known as parasitic integration. This is fundamentally different from a negotiation that creates wealth or value. CPF 1410-12, 1427.

members attempting to justify price-fixing on the ground that prices were fixed reasonably. Moreover, courts have consistently rejected claims that an anticompetitive restraint is justified because it allows for some competition between parties.[30] Lastly, as Professor Bresnahan explained, as a matter of economics, delayed entry is anticompetitive, even if it guarantees entry that is otherwise uncertain. Tr. 34:8085-88 (Bresnahan); CPF 1340-44.

4. The justifications advanced by Professor Willig are implausible

Separate and apart from the rest of its case, Schering's economic expert Professor Willig offered theoretical models that purport to show situations in which a payment to the potential entrant could end up in a settlement that is not anticompetitive. While these models lay out limited conditions under which there are settlements that parties prefer to litigation and that provide more competition than is expected under litigation, none of these models explains why parties would ever reach those "procompetitive" settlements. In fact, the models themselves predict the contrary. CPF 1244-48, 1251-53. For any procompetitive settlement (as defined by the models), there are a multitude of anticompetitive settlements that the parties prefer. Each theory is, therefore, a road-map to anticompetitive conduct: if parties can pay for an entry date, the incumbent will pay more money for a later date. CPF 1233-50.[31]

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[30] *See Socony*, 310 U.S. at 220 ("fact that sales on the spot markets were still governed by some competition is of no consequence" to the determination of the legality of the restraints); *Blackburn v. Sweeney*, 53 F.3d 825, 827 (7th Cir. 1995) ("To fit under the *per se* rule an agreement need not foreclose all possible avenues of competition.").

[31] Some of Professor Willig's models are also implausible because they require at least one party to believe the settlement is anticompetitive. CPF 1254-55. Other models are implausible because they depend on a flawed assumption that Schering was risk averse in its patent settlements (CPF 1238-39, 1241) – an assumption that contradicts the standard view that corporations and their managers try to maximize profits, that multinational corporations can diversify against the risk involved with their business decisions, and that corporations are

Finally, the Willig models are nothing more than post-hoc rationalizations that have nothing to do with the challenged settlements. Schering offered no evidence that these models apply in this case, much less any "empirical evidence of procompetitive effects." *CDA*, 526 U.S. at 775 n.12.[32] Schering provided no evidence that the factual predicates for any of Professor Willig's models existed in either negotiation or that they actually prevented settlement without a payment. CPF 1300-37.[33]

5. Upsher's purported justifications are not plausible

Upsher has raised a hodge-podge of supposed justifications: (1) the payments were a return on Upsher's R&D investment; (2) Upsher obtained a distributor for six of its products; (3) Upsher avoided patent litigation over Klor Con M10 and conserved judicial resources; (4) Upsher's entry resulted in two additional generic entrants; and (5) the settlement accelerated the expiration of the Hatch-Waxman exclusivity period. Upsher never explains, however, how a payment for an entry date furthers any of these so-called justifications as a matter of theory or fact.

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structured to encourage risk-neutral decision making. CPF 1264-77.

[32] *See Indiana Fed'n of Dentists*, 101 F.T.C. 57, 175 (1983) (requiring respondents to support justifications for otherwise anticompetitive restraints with "record evidence"), *vacated* 745 F.2d 1124 (7th Cir. 1984), *rev'd* 476 U.S. 447 (1986).

[33] At times, Schering suggests that some of the facts exist, but it provides no evidence that the negotiations were affected by those facts. For example, there is no evidence that Schering was concerned that Upsher was cash-strapped and would launch at risk. Nor is there evidence that Upsher's payment demand related to concerns about information asymmetry or the fear of a third-party entrant.

6. Schering's additional defenses for its settlement with AHP are not cognizable

Schering sought to justify its payment to AHP by arguing that (i) it would have won the AHP patent case; (ii) its $15 million payment to AHP was small; and (iii) the agreement should be presumed reasonable because of judicial involvement. Each of these justifications fail.

- Whether or not Schering would have won the patent litigation against AHP ignores the anticompetitive effect in this case – the reduction in uncertain competition.

- Even if the size of the payment to AHP was relatively small (at least compared to Upsher's), this would not affect the legality of the agreement. "[L]ong ago the Court rejected the invitation to inquire into the 'reasonableness' of price and output decisions." *Chi. Prof.*, 961 F.2d at 674. An agreement that delays entry is illegal unless there is an off-setting efficiency. Schering has come forward with none.

- Schering's claim that its settlement with AHP is presumptively legal, based on its contention that a magistrate judge "approved" the agreement, is wrong. The magistrate brokered the settlement but had no power to disapprove the agreement reached by the parties. And even if he had approved it, there is no authority for any presumption that would alter the ordinary inquiry into competitive effects.

D. The Restraints Are Also Per Se Illegal

Paying a competitor for agreement on an entry date is a practice that "facially appears to be one that would always or almost always tend to restrict competition and decrease output," and respondents have made no showing that their agreements here were "designed to 'increase economic efficiency and render markets more, rather than less, competitive.'" *BMI*, 441 U.S. at 19-20. The ALJ erred in accepting respondents' contention that the *per se* rule cannot be applied because the agreements involve "novel" restraints and arose in a patent settlement context. ID at 97-100. Payments from a branded drug maker to an allegedly-infringing generic applicant in return for a promise to stay off the market are economically equivalent to market allocation

agreements, and have been held to be *per se* illegal. *Cardizem,* 105 F. Supp. 2d 705-06; *Terazosin Hydrochloride*, 164 F. Supp. 2d at 1349. As the Supreme Court's decisions in *Masonite* and *Singer, supra*, amply demonstrate, that the agreements settled patent litigation does not make *per se* condemnation inappropriate.

Unlike many patent settlements, the challenged agreements are devoid of the kind of efficiencies that can result, for example, when owners combine their conflicting intellectual property so as to produce a product that otherwise would not exist, or when a patent holder and a new entrant compromise and allow the new entrant to come to market in exchange for compensation to the patent holder.[34] Accordingly, the settlement context does not make *per se* treatment inappropriate in this case.

III. The Agreements Constitute Illegal Monopolization and Conspiracies to Monopolize

The offense of monopolization has two elements: (1) "the possession of monopoly power," and (2) "the willful acquisition or maintenance of that power" through exclusionary conduct. *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966). "Monopoly power is the power to control prices or to exclude competition." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956). This power can be shown by "direct proof" of an ability to "profitably raise prices substantially above the competitive level," or by circumstantial evidence

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[34] *See* Federal Trade Comm'n & United States Dep't of Justice, *Antitrust Guidelines for the Licensing of Intellectual Property* at § 3.4 (1995) ("To determine whether a particular restraint in a licensing arrangement is given *per se* or rule of reason treatment, the Agencies will assess whether the restraint in question can be expected to contribute to an efficiency-enhancing integration of economic activity").

of monopoly power based on an examination of market structure. *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (per curium).

When courts assess monopoly power indirectly, they first define a relevant market within which that power might be exercised and then determine whether the firm possesses a dominant share of that market. Market definition is thus a tool to help determine whether monopoly power exists. ALJ Chappell fundamentally misconstrues the purpose of this inquiry by treating market definition as an end in itself and by relying almost exclusively on *Brown Shoe* in doing so. This error led him to ignore abundant direct evidence that generic K-Dur 20's entry would, and did, have significant competitive effects – unlike any other potassium supplement – by taking most of K-Dur 20's sales and lowering the average market price for 20 mEq potassium tablets and capsules. This is the best evidence of the relevant market and Schering's monopoly power.

A. Schering Had Monopoly Power at the Time of the Challenged Agreements

Direct evidence demonstrates that Schering enjoyed substantial pricing power over K-Dur 20 prior to generic entry, and that its agreements with Upsher and AHP to stay off the market had detrimental effects on consumers. This evidence, discussed in Section II above, includes:

1. Schering, Upsher, and AHP all forecast that generic K-Dur 20's entry would quickly take a large share of branded K-Dur 20's sales and would significantly lower the average market price paid for K-Dur 20 and its generics;

2. In the years prior to generic K-Dur 20's entry, sales of branded K-Dur 20 grew compared to the sales of lower-priced potassium supplements, even in the face of Schering's annual relative price increases for K-Dur 20; and

3. When Upsher entered the market with generic K-Dur 20 in September 2001, it sold at half the price of branded K-Dur 20 and generics quickly took more than half of K-Dur 20's sales.

This evidence also demonstrates that the relevant market in which to analyze Schering's agreements with Upsher and AHP is K-Dur 20 and its generic equivalents, because only generic K-Dur is a significant competitive constraint on K-Dur 20. *See, e.g., Coca-Cola Bottling Co. of the Southwest*, 118 F.T.C. 452, 541 (1994) (relevant market defined by those products that are "sufficiently substitutable that they could constrain a small but significant, nontransitory price increase"). Schering thus had monopoly power.

There is no dispute that prior to generic K-Dur 20's entry there were numerous pharmaceutical products that could be used to treat potassium deficiency. But, as the Commission made clear in *Coca-Cola Bottling*, the relevant antitrust inquiry is not whether "certain [products] 'competed' against each other in a broad sense," but instead whether such "products were sufficiently substitutable that they could constrain" significantly each other's pricing.[35] Moreover, a properly defined antitrust market, as a matter of law, need not include all functionally interchangeable products, because the functional interchangeability between products provides only "the outer boundaries of a product market." *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962).[36] When products, like pharmaceuticals, can be used for the

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[35] 118 F.T.C. at 541 (rejecting ALJ's "narrow focus on certain selected pieces of evidence" and reversing initial decision). ALJ Chappell appears to dismiss our reliance on the Commission's decision in *Coca-Cola Bottling* because it "was a merger case" (ID at 89), although *Brown Shoe*, upon which he relies so heavily, also was a merger case.

[36] *See, e.g., Coca-Cola Bottling*, 118 F.T.C. at 538-39, 542, 574 (1994) (excluding generic carbonated soft drinks and all non-carbonated soft drinks from a brand carbonated soft drink market); *Olin Corp.*, 113 F.T.C. 400, 604 (1990) (excluding liquid pool sanitizers from a dry pool sanitizer market); *United States v. Gillette Co.*, 828 F. Supp. 78, 83-84 (D.D.C. 1993) (separating premium writing instruments from other lower-priced writing instruments); *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1075 (D.D.C. 1997) (finding that the sale of consumable office supplies through office superstores constituted a relevant market, even though other sellers of office supplies compete with superstores, and observing that "the mere fact that a firm may be

same purpose but differ in terms of price, quality, consumer preferences, or other significant attributes, the products are considered to be differentiated. And although differentiated products "compete" along some dimensions, as the court recognized in *SmithKline Corp. v. Ely Lilly & Co.*, a case involving pharmaceuticals, a relevant antitrust market should include only those products that "have the ability – actual or potential – to take significant amounts of business away from each other." 575 F.2d 1056, 1063 (3d Cir. 1978).

Record evidence explains why Schering enjoyed its monopoly over K-Dur 20 prior to generic entry. First, as health-plan witness and pharmacist Russell Teagarden testified, health plans keep many different potassium supplements on their formularies not because the products are interchangeable, but rather the opposite:

> [O]ver the years, the decades, there have been a variety of dosage forms that have been engineered to make [potassium] more palatable, acceptable, better tolerated, and patients tend to do better with one or the other, and this happens to be the range that is necessary to find one for a patient to accept.

Tr. 2:207 (Teagarden).

Second, K-Dur 20's unique formulation offered superior convenience to the patient, and potentially greater patient compliance to the physician, because of its ease of dosing and microencapsulation. CPF 1037-70.

Third, and most importantly, before the introduction of generic K-Dur 20, pharmacists were not allowed to automatically substitute other forms of potassium for K-Dur 20. CPF 34, 36, 1006-09. As Professor Bresnahan explained, this imposed what economists call a "switching

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termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant product market for antitrust purposes").

cost" on those seeking to use a non-bioequivalent generic or other potassium product in lieu of K-Dur 20. Tr. 3:490-91 (Bresnahan). CPF 35, 1010-14.

ALJ Chappell, however, dismissed this and other evidence of monopoly power discussed by our economic expert, apparently because Professor Bresnahan did not employ certain methodologies – including price tests, econometric studies, and the measurement of price elasticity – to reach his conclusions. Professor Bresnahan knows these methodologies well, having used them as the Chief Economist at the Department of Justice Antitrust Division and as an economics professor at Stanford University. In fact, Professor Bresnahan pioneered the development of methodologies for measuring market power.[37] Here, however, the direct evidence of anticompetitive effects was so strong that Professor Bresnahan concluded it was not necessary to employ these other methodologies. *See, e.g.*, Tr. 6:1224 (the choice of methodology is a function of "the available body of facts and information"). As he explained:

> Economists define markets in order to establish the area within which competition will decrease prices. A market is an area within which an addition of competition will lower prices or a subtraction of competition, a lessening of competition, will raise prices. . . .
> . . .
>
> Using that principle . . . I defined the market to be . . . K-Dur 20 and generics for it because it was clear that the competition within that class would lower prices, that the removal of competition within that class of products would raise prices, and in neither case trivial. It would raise them and lower them substantially.

Tr. 6:1222-23 (Bresnahan).

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[37] *See, e.g.*, Timothy F. Bresnahan, *Empirical Studies of Industries with Market Power*, *in* 2 Handbook of Industrial Organization 1011 (R. Schmalensee & R. D. Willig, eds.); Jonathan B. Baker & Timothy F. Bresnahan, *Empirical Methods of Identifying and Measuring Market Power*, 61 Antitrust L.J. 3 (1992).

B. Schering Willfully Maintained Its Monopoly through Exclusionary Conduct

The second part of the monopolization test – the willful maintenance of monopoly through exclusionary conduct – is established by the evidence demonstrating that Schering's agreements with Upsher and AHP unreasonably restrained competition, as discussed in Section II above. This conduct is "exclusionary" because it involves "conduct, other than competition on the merits or restraints reasonably 'necessary' to competition on the merits, that reasonably appears capable of making a significant contribution to . . . maintaining monopoly power." *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 230 (1st Cir. 1983) (quoting III Phillip E. Areeda and D. Turner, *Antitrust Law* ¶ 626 at 83 (1978)). And, as the Supreme Court has found, violations of Section 2 of the Sherman Act can be established by proof of restraints of trade that violate Section 1, when those restraints result in the acquisition or maintenance of monopoly power. *United States v. Griffith*, 334 U.S. 100, 108 (1948).[38]

C. Schering's Monopolizing Conduct Had No Legitimate Business Justification

As discussed in Section II.C. above, Schering's agreements with Upsher and AHP to delay generic entry and monopolize the market for K-Dur 20 lacked any legitimate business justification. They were "not motivated by efficiency concerns," *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 610 (1985), did not relate "directly or indirectly to the enhancement of consumer welfare," *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 36 F.3d

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[38] *See also* III Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 651h (2d ed. 2002) ("It is accepted law that a monopolist violates the Sherman Act if it 'has acquired or maintained . . . monopoly . . . by means of those restraints of trade which are cognizable under § 1 [of the Sherman Act].'" (citing *Griffith*)).

1147, 1183 (1st Cir. 1994), and were not the "consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

D. Respondents Entered into Conspiracies to Monopolize

The elements of a conspiracy to monopolize are: (1) the existence of a combination or conspiracy; (2) an overt act in furtherance of the conspiracy; and (3) specific intent to monopolize. *See, e.g., Volvo N. Am. Corp. v. Men's Int'l Prof'l Tennis Council*, 857 F.2d 55, 74 (2d Cir. 1988).

The requisite proof of conspiracy to monopolize is satisfied by the written agreements that Schering entered into with Upsher and AHP. The overt act element is met by various acts, including Schering's payments of $60 million to Upsher and $15 million to AHP, acceptance of the payments by Upsher and AHP, and Upsher's and AHP's forbearance from launching their products.

The specific intent to monopolize element may be shown either by direct evidence of the respondents' state of mind, or by inference from their conduct. *See American Tobacco Co. v. United States*, 328 U.S. 781, 809-10 (1946). The ALJ, having already erroneously rejected the factual premise of the case – that Upsher and AHP promised to forebear competing with K-Dur 20 in exchange for a share of Schering's monopoly profits – quickly and erroneously concluded that the evidence also did not permit an inference of specific intent. ID at 119. There is, however, ample record evidence from which to infer that respondents specifically intended that Upsher and AHP would be compensated for agreeing not to challenge Schering's monopoly for several years, including evidence that:

- Schering, Upsher, and AHP knew that a generic K-Dur 20 would have a significant adverse effect on branded K-Dur 20's sales (Part II.B.1).
- Upsher and AHP asked for compensation from Schering for agreeing to stay off the market, basing their demands on an analysis of Schering's potential financial losses as a result of their entry (Part I).
- Schering knew it had to compensate Upsher and AHP for staying off the market (Part I).
- Schering paid Upsher and AHP million of dollars to stay off the market (Part II).
- Upsher and AHP stayed off the market with their generic K-Dur 20 products (Part II).

IV. The ALJ Improperly Excluded Evidence

Complaint counsel request that the Commission vacate four rulings by ALJ Chappell that excluded significant rebuttal evidence. These rulings were abuses of discretion and deprived the Commission (and any reviewing court) of relevant, reliable, and probative evidence. The current record proves the violations charged here, but if these erroneous rulings stand they will establish harmful precedents for ALJs in future cases. Moreover, given the importance of this case, the Commission and any reviewing court should have as complete a record as possible. The Commission has "all the powers which it could have exercised if it had made the initial decision," (Rule 3.54(a)), and can devise an efficient and fair procedure to take testimony excluded as a result of the ALJ's erroneous rulings.

A. Refusal to Grant Relief Against Upsher's Interference with Complaint Counsel's Access to a Third-Party Witness

ALJ Chappell ignored unrebutted evidence that Upsher counsel invoked a private confidentiality agreement to induce a witness to stop cooperating with complaint counsel. In

response to Upsher's claim that its supplier's capacity restraints would have prevented it from entering the market before September 2001, we planned to call a witness from that supplier, International Processing Corporation ("IPC"). IPC had agreed to cooperate with complaint counsel, but cancelled the meeting after a discussion with Upsher counsel Christopher Curran. As explained in the declaration of FTC attorney Robin Moore, IPC's attorney informed her that Mr. Curran had "strongly urged him to not allow IPC employees to talk to complaint counsel,"[39] and told him that talking to us might violate a confidentiality agreement between Upsher and IPC and "prejudice" Upsher.[40] IPC stated that but for Upsher's opposition, it would have cooperated voluntarily with both complaint counsel and Upsher.[41]

Upsher did not deny Ms. Moore's description of this conversation with IPC's counsel.[42] Instead, Upsher expressed "concern" regarding "Complaint Counsel's attempt to hold informal *ex parte* interviews [with IPC employees], without Upsher-Smith being represented and a proper record being made."[43] But Upsher's confidentiality agreement gave it no right to interfere with witnesses who were otherwise willing to cooperate with complaint counsel. As the court observed in *EEOC v. Astra USA, Inc.*, 94 F.3d 738, 744 (1st Cir. 1996), in affirming an

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[39] *Emergency Motion for Order That Upsher-Smith Withdraw Objection to IPC Communicating with Complaint Counsel*, Attachment A, Declaration of Robin Moore (December 12, 2001) ¶ 5.

[40] *Id.* ¶¶ 3, 4.

[41] *See id.* ¶ 6.

[42] *See Upsher-Smith's Opposition to Complaint Counsel's "Emergency" Motion Regarding IPC* (December 26, 2001).

[43] *Id.* at 2.

injunction against enforcement of a settlement agreement that prohibited a settling party from cooperating with EEOC investigators, it is "overwhelmingly clear" that a provision that impedes full and open communication with enforcement officials "offends public policy." Noting that it would be "most peculiar" to force an enforcement agency in such circumstances to use its subpoena power, the court held that "[s]uch a protocol would not only stultify investigations but also significantly increase the time and expense" of enforcement efforts. *Id.* at 745.

After learning of Upsher's actions regarding the IPC witness, we promptly filed an emergency motion before ALJ Chappell, seeking an order requiring Upsher to advise IPC that it had no objection to IPC's voluntary cooperation with FTC staff.[44] Such relief was found appropriate, for example, in *Davis v. Dow Corning Corp.*, 530 N.W.2d 178 (Mich. Ct. App. 1995), where the court upheld a protective order requiring plaintiffs' counsel to withdraw their request that certain physicians not speak to defendant's counsel unless a plaintiffs' attorney was present. *Id.* at 181 (protective order "an appropriate means of ensuring that neither plaintiffs not their attorneys were permitted to influence the treating physicians to refuse to engage in any *ex parte* interviews"). Rule 3.4(f) of the ABA's Model Rules of Professional Conduct and the rules of the District of Columbia Bar, provide that, except in cases involving employees or relatives of a client, a lawyer shall not "request a person other than a client to refrain from voluntarily giving relevant information to another party."[45]

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[44] *Emergency Motion for Order That Upsher-Smith Withdraw Objection to IPC Communicating with Complaint Counsel* (December 12, 2001).

[45] *ABA/BNA Lawyer's Manual on Professional Conduct* §§ 61:702; 61:715; 61:728 (1997); District of Columbia Bar, D.C. Rules of Professional Conduct, III-3 (2001).

Six weeks later, when ALJ Chappell ruled on our emergency motion, he ignored Upsher's conduct altogether, and instead ruled that "IPC will not be compelled to provide Complaint Counsel with informal interviews of its employees" – relief we had not sought.[46]

After this ruling, we requested leave to depose the IPC employee.[47] ALJ Chappell denied this motion as well, stating that no "good cause" had been shown for a deposition of an IPC employee after the November 2001 discovery deadline (Tr. 9:1961) – apparently on the ground that we should have anticipated Upsher's conduct and the ALJ's refusal to address it. Finally, on the eve of the rebuttal case, the ALJ summarily denied our renewed request that Upsher be ordered to cease its interference with our access to the IPC witness. Tr. 30:7481-83.

The ALJ's rulings were plain error and an abuse of discretion. As the Supreme Court stated in *Town of Newton v. Rumery*, 480 U.S. 386, 392 (1987), it is "well-established" that "a promise is unenforceable if the interest in its enforcement is outweighed in the circumstances by a public policy harmed by enforcement of the agreement." As in *EEOC v. Astra,* the public interest in FTC law enforcement outweighs Upsher's interest in enforcing its private contract against IPC in this context. Upsher had no justification that trumps the public interest in efficient law enforcement, because the information it sought to shield is not privileged, and any concerns about protecting confidential commercial information could be addressed by a protective order. Since the contract was unenforceable, Upsher's encouraging IPC not to cooperate with complaint counsel was no different than any party's attempt to dissuade a third-party witness from

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[46] *Order Denying Complaint Counsel's Motion on Interviewing of IPC Employees,* at 2 (January 22, 2002).

[47] *See Emergency Motion for Leave to Depose Mike Valazza* (January 25, 2002).

cooperating with opposing counsel, and the ALJ should have ordered Upsher to withdraw its objection to IPC's cooperation with FTC staff, just as the court did in *Davis v. Dow*, 530 N.W.2d at 181.

If not corrected, the ALJ's rulings on the IPC witness – allowing Upsher to use a private confidentiality agreement to obtain silence from a witness possessing relevant, non-privileged information – will encourage others to adopt this technique to thwart future Commission investigations and enforcement proceedings. We therefore urge the Commission to: (1) correct the ALJ's rulings regarding Upsher's dealings with IPC; (2) provide complaint counsel with the requested relief, to wit, an order requiring Upsher to notify IPC that it has no objection to IPC meeting informally with complaint counsel, and, if necessary, an order for a deposition of the IPC employee; and (3) reopen the record to permit IPC testimony to be admitted.

B. Exclusion of Expert Testimony by Professor Bresnahan Concerning Pharmaceutical Industry Substitution Data

ALJ Chappell erroneously barred rebuttal testimony from complaint counsel's economic expert, Professor Timothy Bresnahan, about CX 43, a Schering document already in evidence, which contains "National Prescription Audit" data on prescription and substitution patterns compiled by IMS Health. Professor Bresnahan would have explained that the data in CX 43 demonstrate, contrary to the testimony by respondents' witnesses, that K-Dur 20 prescriptions were almost never filled with two Klor Con 10s.

CX 43 is a 28-page document containing five years of detailed data, and expert testimony analyzing this data would have assisted the Commission as trier of fact in understanding this record evidence. The proffered testimony accordingly meets the standards of Fed. R. Evid. 702.

Furthermore, under Fed. R. Evid. 703, the data in CX 43 are an appropriate basis for Professor Bresnahan's opinion testimony, because they are "of a type reasonably relied upon by experts in the particular field." *See, e.g., Daubert v. Merrell Pharms.*, 509 U.S. 579, 595 (1993). IMS National Prescription Audit data (which includes substitution data) have long been relied upon in economic literature concerning pharmaceutical markets.[48]

The ALJ nonetheless excluded Professor Bresnahan's testimony on the ground that he was "not qualified to proffer an opinion on specific substitutability." *See* Tr. 34:8052, 8122-23.[49] ALJ Chappell made no finding that economists do not reasonably rely on the type of data contained in the IMS National Prescription Audit,[50] and his statement that Professor Bresnahan is not qualified to proffer an opinion on "specific substitutability" is incomprehensible. His later statement that his ruling "stands . . . based on the voir dire of [Upsher counsel] Mr. Gidley," (Tr. 34:8122-23), likewise provides no basis for excluding the testimony. The matters raised in Mr. Gidley's voir dire (*e.g.*, that Professor Bresnahan is not a pharmacist or a physician) go – if anything – to the weight to be accorded the testimony, not its admissibility.[51]

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[48] *See, e.g.* Alison Masson & Robert L. Steiner, Federal Trade Commission, *Generic Substitution and Prescription Drug Prices*, 272-74 (1985); Caves, *supra* note 44, at 6-7, 15.

[49] Although the ALJ initially also excluded testimony concerning CX 43 on the ground that the document was not cited in Professor Bresnahan's report, he later revised his ruling. *See* Tr. 34:8122-23 (noting that CX 43 was in evidence, "but my ruling stands, that I wasn't going to allow him to analyze it based on the voir dire of [Upsher counsel] Mr. Gidley.").

[50] The ALJ ruled immediately after Mr. Gidley's voir dire, without giving complaint counsel any chance to demonstrate that economists rely on such data. *See* Tr. 34:8052.

[51] *See, e.g., United States v. Vallejo,* 237 F.3d 1008, 1021 (9th Cir. 2001); *Hurst v. United States*, 882 F.2d 306, 311 (8th Cir. 1989).

The ALJ's ultimate ruling that Schering lacked monopoly power – based in part upon his finding that substitution was significant (*see, e.g.*, IDF 59, 70, 77) – demonstrates that his exclusion of Professor Bresnahan's testimony was material and unfairly prejudicial. Unlike the flimsy evidence on which these ALJ findings are based, Professor Bresnahan would explain that the empirical data in the record – industry substitution data that both Schering and Upsher purchased and relied upon[52] – show that such substitution almost *never* occurs at the pharmacy level and was not significant at the physician level. If permitted to testify, Professor Bresnahan would have explained that:

- IMS Health collected the data in CX 43 to measure substitution by pharmacists for a given product. The data collection methods and statistical measures used by IMS are reliable. (CX 1792 (proffered testimony of Professor Bresnahan) at ¶ 9).

- The data in CX 43 directly refute the testimony by Dr. Addanki and others that there was significant substitution between K-Dur 20 and other potassium products (¶ 14).

- According to the IMS Health data, for the years 1996 through 2000, at least 99.9% of all K-Dur 20 prescriptions were filled with K-Dur 20 (¶¶ 18-22).

- The data in CX 43 also contradict claims that there was significant substitution from K-Dur 20 occurring at the physician level. The data show that from 1996 through 2000, the proportion of all new potassium prescriptions written for K-Dur 20, and its share of all dispensed potassium prescriptions, increased relative to all other potassium products (¶¶ 14, 23).

The ALJ's improper exclusion of this reliable and probative evidence allowed respondents' faulty assertions to go unrebutted, creating a one-sided record. We therefore request that the Commission reverse the ALJ's ruling, and reopen the record to allow testimony

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[52] *See, e.g.*, CX 13 at SP003044; CX 75 at USL142387.

from Professor Bresnahan regarding the empirical data in CX 43 showing the virtual absence of substitution away from K-Dur 20 prior to the introduction of Upsher's generic.

C. Exclusion of Expert Rebuttal Testimony of Professor Bazerman Concerning Risk Aversion

The ALJ abused his discretion when he excluded certain rebuttal testimony of Harvard Business School Professor Max Bazerman on the ground that complaint counsel submitted his supplemental expert report after the deadline for rebuttal reports. This drastic sanction was imposed without regard to well-established legal standards for excluding evidence as a penalty for disclosures made after scheduling order deadlines, and resulted in substantial unfairness at trial.

The key issues in deciding whether to exclude evidence based on a failure to make timely disclosures are the likely prejudice to the opposing party, and the extent to which that prejudice can be cured without unduly delaying the proceedings. *See, e.g., ABB Air Preheater, Inc. v. Regenerative Envtl. Equip. Co.*, 167 F.R.D. 668, 672 (D.N.J. 1996) (prejudice is "pivotal issue" in considering drastic remedy of exclusion); *PepsiCo, Inc.*, 83 F.T.C. 538, 544-45 (1973) (reversing ALJ ruling denying complaint counsel's request to offer additional witnesses and new exhibits after close of case-in-chief). In *Bankers Life & Cas. Co.*, ALJ Parker denied respondents' motion to strike four expert witnesses, despite the delay in producing their expert reports. Finding no prejudice, he observed that "the public interest in presenting essential, relevant evidence in Commission proceedings outweighs, in this instance, respondents' right to compliance by the staff with my prehearing order." 1979 FTC LEXIS 537 at *2-3 (1979).

Four factors are pertinent in determining whether exclusion is warranted: the extent of prejudice to the resisting party; the ability to cure it by means other than exclusion; the degree of disruption of the trial; and the bad faith or willfulness of the party offering the evidence. *See, e.g., Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791 (3d Cir. 1994); *Woodworker's Supply, Inc. v. Principal Mut. Life Ins., Inc.*, 170 F.3d 985, 993 (10th Cir. 1999).[53] None of these factors is present here. There was no prejudice to respondents. Following respondents' submission of nineteen expert reports in October 2001, complaint counsel served expert rebuttal reports on November 15, 2001, including one by Professor Bazerman, a leading expert in the field of negotiations. Professor Bazerman addressed the economic justifications proffered in respondents' expert reports, with emphasis on the negotiation process. He stated that, while the analyses of respondents' economists showed that "risk preferences" and other factors "could theoretically create a situation where a settlement between the branded firm and the generic firm could be pro-competitive," a settlement with a payment from the branded firm to the generic in fact was more likely to be anticompetitive. CX 755 (not in evidence) at 4.

At his December 2001 deposition, Professor Bazerman was asked about his review of respondents' economists' reports. He explained that empirical research on risk preferences shows that a fundamental premise of respondents' experts – that Schering was risk averse in settlement negotiations with Upsher and AHP – is not a valid assumption.[54] Although he referred

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[53] *See* Fed. Rule Civ. P. 37(c)(1) (exclusion of evidence where litigant fails to make required disclosures authorized, but not if failure is substantially justified or if non-disclosure was harmless).

[54] *Complaint Counsel's Opposition to Respondents' Joint Motion to Strike the Supplemental Expert Report and Related Testimony of Professor Max H. Bazerman* (January 31, 2002), Attachment A (Bazerman Dep. at 178-80).

to risk preferences in his original report, Professor Bazerman explained that he had not thought to discuss the scholarly literature concerning risk preferences.[55] At his deposition, however, he described this well-established body of empirical research and why it leads to the conclusion that economic actors facing losses tend to be "risk-seeking," not risk averse.[56]

Professor Bazerman thus put respondents on notice, through his deposition testimony, of additional bases for his opinion, and followed up with a brief supplemental report prior to trial, on January 14, 2002. We also offered to make Professor Bazerman available for another deposition. Respondents chose instead to file a motion to strike. (By contrast, when a Schering expert supplemented his report a few days before trial, we accepted Schering's offer to take a mid-trial deposition.)

Respondents thus declined this opportunity to cure any possible prejudice, but availed themselves of another by having their experts express new opinions in reply to Professor Bazerman's supplemental report during their case-in-chief.[57] After admitting this new evidence – sometimes over complaint counsel's objection – ALJ Chappell granted the motion to strike, which had been pending for six weeks. He based his ruling solely on the grounds that (1) the supplemental report was filed after the deadline for expert rebuttal reports; and (2) complaint counsel knew before the close of discovery that risk aversion was an element of respondents'

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[55] *Id.* at 180.

[56] *Id.* at 185-86.

[57] Respondents' experts had opined in their reports that, in essence, everyone is always risk averse, but at trial they took the position that patent holders facing losses were more likely to be risk averse than alleged infringers. *See* Tr. 29:7071-73 (O'Shaughnessy); Tr. 24:5776-78 (Addanki).

defense. *See* Tr. 32:7811-12. ALJ Chappell made no finding of any abuse of the discovery process by complaint counsel, of prejudice that could not be cured, or of undue delay at trial. In short, he found *none* of the factors that would support the extreme remedy imposed by his ruling.

The ALJ's ruling creates a distorted factual record and sets a precedent at odds with well-established legal principles. We request that this ruling be reversed, and that we be allowed to present testimony proffered by Professor Bazerman (Tr. 36:8523-8550) that:

- Numerous empirical studies have demonstrated the validity of "Prospect Theory," which holds that individuals deviate from "risk neutrality" depending on whether they view the uncertainty as a potential loss or gain.
- When losses were involved, parties were risk seeking; when gains were involved, they were risk averse.
- Schering managers viewed the K-Dur 20 litigation as a potential for loss, not a potential for gain. Thus, if they were to deviate from risk neutrality (the standard assumption) in settling the K-Dur 20 litigation, they would more likely deviate towards being risk seeking, not risk averse.

D. Exclusion of Rebuttal Testimony from Walgreens

ALJ Chappell improperly denied complaint counsel's request to add a rebuttal witness from Walgreens, the nation's largest chain drugstore, after an Upsher witness gave unexpected and incorrect trial testimony that Walgreens had mandated or promoted what is often referred to as "therapeutic interchange." Tr. 20:4682-83 (Dritsas). In contrast to "generic substitution," which refers to a pharmacist substituting an AB-rated generic version when presented with a prescription for a branded drug, "therapeutic interchange" is the dispensing of an alternative product that is not an AB-rated generic, but that the pharmacist considers therapeutically equivalent. Respondents' claim that Schering lacked monopoly power was based in part upon

assertions that Upsher successfully encouraged pharmacists to undertake therapeutic interchange and substitute two Klor Con 10s for one K-Dur 20.

In response to Mr. Dritsas's surprising testimony, complaint counsel sought to offer the rebuttal testimony of William Groth, a knowledgeable Walgreens executive, that:

- Walgreens never instituted any policy to mandate substituting two Klor Con 10 tablets when K-Dur 20 was prescribed.
- Walgreens' policy is not to promote therapeutic interchange, because state laws require a pharmacist to obtain approval from the physician before instituting a therapeutic interchange. Obtaining such approval is costly for the pharmacist, due to the time the pharmacist must devote to the task and the risk of loss of physician good will.[58]

ALJ Chappell denied our motion to add Mr. Groth as a rebuttal witness, holding that because we touched on "the issue of substitution" at Mr. Dritsas's deposition, "[t]his issue was not a surprise" and accordingly no "good cause" had been shown to add Mr. Groth as a rebuttal witness. Tr. 31:7491-92. Awareness that substitution was an issue in the case, however, would provide no basis to anticipate that testimony of a pharmacy chain would be needed to correct inaccurate assertions made by Mr. Dritsas for the first time at trial. At his deposition, he made no mention either of Walgreens or the policies of pharmacy chains regarding therapeutic interchange. Nor did he state that pharmacists could simply fill a K-Dur 20 prescription with another product – a therapeutic interchange – without getting authorization from the doctor. To the contrary, he stated that 8 and 10 mEq potassium chloride tablets are *not* interchangeable with 20 mEq tablets at the pharmacy level (CX 1496 at 56:10-21 (Dritsas dep.)), and that a pharmacist

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[58] *Complaint Counsel's Motion for Leave to Call William Groth as a Rebuttal Witness* 2, 3 (March 8, 2002); *see also* CX 1778 ¶¶ 11-14 (Groth Declaration) (not admitted).

would need approval from the physician to switch from a 20 mEq tablet to another form or dosage strength (CX 1496 at 56:17-57:19 (Dritsas dep.)).

The ALJ's ruling was clearly erroneous. The Walgreens testimony is classic rebuttal – it is evidence "designed to meet facts not raised before defendant's case in chief."[59] Moreover, the ALJ erred in excluding this testimony without considering whether allowing it would result in incurable prejudice to respondents. As we have already discussed, that is a critical issue to weigh before imposing the drastic sanction of excluding testimony.[60] Upsher put the therapeutic interchange policies of pharmacy chains directly at issue in Mr. Dritsas's trial testimony. Having opened the door, Upsher could hardly claim prejudice when complaint counsel sought to call a witness from Walgreens to expose Mr. Dritsas's misstatements.

The ALJ's exclusion of Mr. Groth's testimony unfairly prejudices complaint counsel's case because it leaves Mr. Dritsas's inaccurate testimony about the policies of Walgreens and other pharmacy chains unrebutted, and his credibility unchallenged. In his product market findings, the ALJ relied heavily on Mr. Dritsas's testimony concerning therapeutic interchangeability and switching, *see, e.g.*, IDF 41, 44-46, 59, 70-72, 74-75 (all citing Mr. Dritsas), and the record on this issue is improperly one-sided because of the ALJ's erroneous ruling. We therefore request that the record be reopened to take Mr. Groth's testimony.

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[59] *Rodriguez v. Olin Corp.*, 780 F.2d 491, 496 (5th Cir. 1986).

[60] *See* cases cited at 85-86, *supra*.

CONCLUSION

For the foregoing reasons, we respectfully request that the Commission:

1. Vacate the Initial Decision and four rulings by ALJ Chappell that excluded important rebuttal evidence.

2. Adopt complaint counsel's proposed findings of fact and conclusions of law.

3. Reopen the record to take testimony that was improperly excluded, and then issue the attached order.

Respectfully Submitted,

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Dated: August 9, 2002

APPENDIX A

ORDER

I.

IT IS ORDERED that for the purposes of this Order, the following definitions shall apply:

A. "Respondent Schering" means Schering-Plough Corporation, its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Schering-Plough Corporation, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

B. "Respondent Upsher" means Upsher-Smith Laboratories, Inc., its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Upsher-Smith, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

C. "Commission" means the Federal Trade Commission.

D. "180-day Exclusivity Period" means the period of time established by section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(5)(B)(iv) (2002)).

E. "AB-rated Generic Version" means an ANDA found by the Food and Drug Administration to be bioequivalent to the Referenced Drug Product, as defined under 21 U.S.C. § (j)(8)(B) (2002).

F. "Agreement" means anything that would constitute an agreement under Section 1 of the Sherman Act, 15 U.S.C. § 1 (2002) or Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45 (2002).

G. "ANDA" means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j).

H. "ANDA Filer" means a party who has filed an ANDA with the FDA.

I. "ANDA First Filer" means the party whom the FDA determines is and remains entitled to, or eligible for, a 180-day Exclusivity Period which has not expired.

J. "ANDA Product" means the product to be manufactured under the ANDA that is the subject of the Patent Infringement Claim.

K. "Drug Product" means a finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients, as defined in 21 C.F.R. § 314.3(b).

L. "Effective Date" means the date of entering into the Agreement.

M. "Expiration Date" means 180 days after the date that the ANDA First Filer commences commercial marketing of (1) the ANDA Product, (2) the Reference Drug Product, or (3) any other AB-Rated Generic Version of the Reference Drug Product.

N. "FDA" means the United States Food and Drug Administration.

O. "NDA" means a New Drug Application, as defined under 21 U.S.C. § 355(b).

P. "NDA Holder" means: (1) the party that received FDA approval to market a Drug Product pursuant to an NDA, (2) a party owning or controlling enforcement of the patent(s) listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the "FDA Orange Book") in connection with the NDA, or (3) the predecessors, subsidiaries, divisions, groups and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (1) and (2) above (such control to be presumed by direct or indirect share ownership of 50% or greater), as well as the licensees, licensors, successors, and assigns of each of the foregoing.

Q. "Patent Infringement" means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.

R. "Patent Infringement Claim" means any allegation made to an ANDA Filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA Product may infringe any patent held by, or exclusively licensed to, the NDA holder of the Reference Drug Product.

S. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

T. "Reference Drug Product" means the Drug Product identified by the ANDA applicant as the Drug Product upon which the ANDA Filer bases its ANDA.

U. "Relinquish" means abandon, waive, or relinquish.

V. "Sale of Drug Products" means the sale of Drug Products in or affecting commerce, as commerce is defined in section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44 (2002).

II.

IT IS FURTHER ORDERED that in connection with the Sale of Drug Products each Respondent shall cease and desist, directly or indirectly, from being a party to any Agreement resolving or settling a Patent Infringement Claim in which:

A. an ANDA Filer receives anything of value, and

B. the ANDA Filer agrees not to research, develop, manufacture, market, or sell, the ANDA Product for any period of time.

PROVIDED, HOWEVER, that nothing in this Paragraph shall prohibit a resolution or settlement of a Patent Infringement Claim in which:

(1) a Respondent is either the NDA Holder or the ANDA Filer;

(2) the value paid by the NDA Holder to the ANDA Filer as a part of the resolution or settlement of the Patent Infringement Claim includes no more than (1) the right to market the ANDA Product prior to the expiration of the patent that is the basis for the Patent Infringement Claim, and (2) the lesser of the NDA Holder's expected future litigation costs to resolve the Patent Infringement Claim or $2 million; and

(3) Respondent has notified the Commission, as described in Paragraph VI.

III.

IT IS FURTHER ORDERED that, when a Respondent makes or is subject to a Patent Infringement Claim in which such Respondent is either the NDA Holder or the ANDA Filer, Respondent shall cease and desist, in connection with the Sale of Drug Products, from being a party to any Agreement in which the ANDA Filer agrees to refrain from researching, developing, manufacturing, marketing, or selling any Drug Product that:

A. could be approved for sale by the FDA pursuant to an ANDA; and

B. is neither the subject of any written claim or allegation of Patent Infringement nor supported by a good faith opinion of counsel that the Drug Product would be the subject of such a claim or allegation if disclosed to the NDA Holder.

IV.

IT IS FURTHER ORDERED that each Respondent shall cease and desist, directly or indirectly, in connection with the Sale of Drug Products, with respect to which such Respondent is either an NDA Holder or the ANDA First Filer for the Reference Drug Product(s), from being a party to any Agreement in which:

A. one party is an NDA Holder and the other party is the ANDA First Filer for the Reference Drug Product, and

B. the ANDA First Filer is prohibited by such Agreement from Relinquishing, or is subject to a penalty, forfeiture, or loss of benefit, if it Relinquishes its right to the 180-day Exclusivity Period.

PROVIDED, HOWEVER, that nothing in this Section shall prohibit any Agreement where the following three conditions are all met:

(1) within twenty (20) days of the Effective Date of the Agreement, the ANDA First Filer commences commercial marketing of the ANDA Product, the Reference Drug Product, or any other AB-rated Generic Version of the Reference Drug Product;

(2) one of the following two conditions has been satisfied:

(a) the 180-day Exclusivity Period, if any, has been triggered and begun to run with respect to the ANDA Product; or

(b) within ten (10) days of the commercial marketing of a Drug Product other than the one subject to the ANDA, the ANDA First Filer has notified the FDA, in writing, that it will Relinquish any and all eligibility for, and entitlement to, a 180-day Exclusivity Period, if any, for the ANDA Product, beyond the Expiration Date; and

(3) Respondent has notified the Commission, as described in Paragraph VI.

V.

IT IS FURTHER ORDERED that, in any instance where a Respondent is a party to a Patent Infringement lawsuit in which it is either the NDA Holder or the alleged infringer ANDA Filer, such Respondent shall cease and desist, directly or indirectly, in connection with the Sale of Drug Products, from being a party to any Agreement in which:

1. the parties do not agree to dismiss the litigation,

2. the NDA Holder provides anything of value to the alleged infringer, and

C. the ANDA Filer agrees to refrain during part or all of the course of the litigation from selling the ANDA Product, or any Drug Product containing the same active chemical ingredient as the ANDA Product.

PROVIDED, HOWEVER, such an Agreement is not prohibited by this Order when entered into in conjunction with a joint stipulation between the parties that the court may enter a preliminary injunct[illegible]suant to Rule 65 of the Federal Rules of Civil Procedure, Fed. R. Civ. P. 65, if:

(1) together with the stipulation for a preliminary injunction Respondent provides the court the proposed Agreement, as well as a copy of the Commission's complaint, and Order in this matter;

(2) Respondent has notified the Commission, as described in Paragraph VI, least thirty (30) days prior to submitting the stipulation for a preliminary injunction;

(3) Respondent does not oppose any effort by the Commission to participate, in any capacity permitted by the court, in the court's consideration of any such action for preliminary relief; and

(4) (a) the court issues an order and the parties' agreement conforms to said order; or

(b) the Commission determines, at the request of Respondent, that entering into the stipulation would not raise issues under Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. Nothing in paragraph V shall be interpreted to prohibit or restrict the right of Respondent to unilaterally seek relief from the court (including but not limited to, applying for preliminary injunctive relief or seeking to extend, or reduce, the 30-month stay pursuant to 21 U.S.C. § 355(j)(5)(B)(iii)).

VI.

IT IS FURTHER ORDERED that Respondent shall:

A. notify the Commission as required by Paragraphs II, IV, and V in the form of a letter ("Notification Letter") submitted to the Secretary of the Commission and containing the following information:

(1) the docket number and caption name of this Order;

(2) a statement that the purpose of the Notification Letter is to give the Commission prior notification of a proposed Agreement as required by this Order;

(3) identification of the parties involved in the proposed Agreement;

(4) identification of all Drug Products involved in the proposed Agreement;

(5) identification of all persons to the extent known who have filed an ANDA with the FDA (including the status of such application) for any Drug Product containing the same chemical entity(ies) as the Drug Product(s) involved in the proposed Agreement;

(6) a copy of the proposed Agreement;

(7) identification of the court, and copy of the docket sheet, for any legal action which involves either party to the proposed Agreement and relates to any Drug Product(s) containing the same chemical entity(ies) involved in the Agreement; and

(8) all documents which were prepared by or for any officer(s) or director(s) of Respondent for the purpose of evaluating or analyzing the proposed Agreement.

B. Submit the Notification Letter to the Secretary of the Commission at least thirty (30) days prior to consummating the proposed Agreement (hereinafter referred to as the "First Waiting Period").

C. If the Notification Letter is provided pursuant to:

(1) Paragraph II, representatives of the Commission may make a written request for additional information or documentary material (as if the

request were within the meaning of 16 C.F.R. § 803.20) prior to expiration of the First Waiting Period. If such a request for additional information is made, Respondent shall not execute the proposed Agreement until expiration of thirty (30) days following complete submission of such additional information or documentary material.

(2) Paragraphs IV or V, Respondent may execute the proposed Agreement upon expiration of the First Waiting Period.

Early termination of the First Waiting Periods in this Paragraph VI may be requested from the Director of the Commission's Bureau of Competition.

VII.

IT IS FURTHER ORDERED that each Respondent shall file a verified written report within sixty (60) days after the date this Order becomes final, annually thereafter for five (5) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require, setting forth in detail the manner and form in which Respondent intends to comply, is complying, and has complied with this Order. Each Respondent shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with this Order.

VIII.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least thirty (30) days prior to any proposed change in Respondent such as dissolution, assignment, sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in Respondent that may affect compliance obligations arising out of this Order.

IX.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order and subject to any legally recognized privilege or immunity, and upon written request with reasonable notice to Respondents, Respondents shall permit any duly authorized representative of the Commission:

A. Access, during office hours and in the presence of counsel, to all facilities, and to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in their possession or under their control relating to compliance with this Order; and

B. To interview officers, directors, employees, agents, and other representatives of Respondents, who may have counsel present regarding such compliance issues.

X.

IT IS FURTHER ORDERED that this Order shall terminate ten (10) years from the date this Order becomes final.

APPENDIX B

Glossary of Terms

1. **AB-rated generic** - A generic drug that has been demonstrated to the FDA to be bioequivalent to a reference drug.

2. **ANDA** - Abbreviated New Drug Application. An applicant seeking to market a generic version of a pioneer drug may submit an abbreviated new drug application. Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA), an applicant is no longer required to submit safety and effectiveness data, but instead may rely on the FDA's prior findings of safety and efficacy of the referenced drug product, so long as it can demonstrate that its generic drug is bioequivalent to the referenced drug product.

3. **Bioequivalent** - A generic drug is bioequivalent to a referenced drug product when (1) it has the same active ingredients as its branded counterpart, and (2) the rate and extension of absorption of its active ingredients fall within established parameters when compared to that of the referenced drug product.

4. **Generic Substitution** - A pharmacist's dispensing of an AB-rated generic when presented with a prescription for a branded drug, as is permitted by the laws of most states.

5. **Hypokalemia** - Potassium deficiency treated with potassium supplements such as K-Dur 20.

6. **K-Dur 20** - Brand name of widely-prescribed potassium chloride supplement sold by Schering-Plough.

7. **Klor-Con M20** - Upsher-Smith's AB-rated generic equivalent of Schering's K-Dur 20.

8. **Microencapsulated** - Refers to a drug made with a process by which individual particles of the active ingredient are coated for the purpose of ensuring a slow, sustained release of that ingredient at controlled rates over a long period of time.

9. **Milliequivalent (mEq)** - A measure of the amount of potassium chloride in a particular dosage form of a potassium chloride supplement.

10. **NDA** - New Drug Application. Under the FDCA, any applicant seeking to market a "new" or pioneer drug must first obtain FDA approval through the filing of a new drug application. An NDA applicant is required to provide, among other items, "full reports of the investigations" that demonstrate a drug product to be

safe and effective for its intended use. The NDA applicant is required to submit to the FDA information on any patent covering the drug, or any method of using the drug for treatment of disease, for which a claim of patent infringement could reasonably be asserted against an unauthorized party. The FDA then lists the approved drug and related patents in its publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the "Orange Book."

11. **Niacin** - Class of pharmaceutical agents used for lowering cholesterol. This class includes Niacor-SR and Niaspan.

12. **Niacor-SR** - Upsher-Smith developmental product intended to be used as a sustained-release niacin product for the treatment of elevated cholesterol.

13. **Niaspan** - Sustained release niacin product sold by Kos Pharmaceuticals.

14. **Paragraph IV Certification** - The ANDA applicant must provide a certification to the FDA with respect to each patent listed in the Orange Book. A paragraph IV certification asserts that such patent is invalid or will not be infringed" by the manufacture, use, or sale of the drug product for which the ANDA is submitted.

15. **Tentative Approval of ANDA** - After all components of an ANDA are found to be acceptable, an approval or tentative approval letter is issued to the applicant. If the approval occurs prior to the expiration of the 180-day exclusivity or 30-month stay, a tentative approval letter is issued and final approval is delayed until the exclusivity or stay has expired. A tentative approval does not allow the applicant to market the generic drug product.

16. **Therapeutic Interchange** - A pharmacist's dispensing of a product (other than an AB-rated generic) that he or she deems to be therapeutically equivalent to the prescribed drug; this requires approval by the prescribing physician.

17. **30-month Stay** - Under the Hatch-Waxman Amendments, if the patentee, upon receiving notice of a Paragraph IV certification, files a patent infringement suit against the certifying ANDA filer within 45 days of such notice, FDA approval of the ANDA is automatically stayed until the earlier of (1) the expiration of 30 months from the patentee's receipt of notice of the Paragraph IV certification, (2) entry of a determination of non-infringement in patent infringement litigation (currently interpreted by the FDA as including litigation involving any ANDA filer), or (3) the date the patent expires.

18. **180-day Exclusivity Right** - Under the Hatch-Waxman Amendments, as currently implemented by the FDA, the first applicant submitting an ANDA which

contains a paragraph IV certification is protected from competition from subsequent generic versions of the same drug product for a period of 180 days after the earlier of the first commercial marketing of the first applicant's drug, or a decision of a court holding the patent that is the subject of the paragraph IV certification to be invalid or not infringed.

19. **'743 Patent** - Patent held by Schering-Plough that relates to specified amounts of coating materials used in potassium chloride supplements. The coating slowly releases the potassium chloride over time, making it a sustained release product.

CERTIFICATE OF SERVICE

I, Patricia A. Allen, hereby certify that on the 9th day of August 2002:

I caused one original and twelve copies of Complaint Counsel's "Appeal Brief of Counsel Supporting the Complaint" [Public Version] to be served by hand delivery, and one copy to be served by electronic mail, upon:

Office of the Secretary
Federal Trade Commission
Room H-159
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

I caused copies of Complaint Counsel's "Appeal Brief of Counsel Supporting the Complaint" [Public Version] to be served upon the following persons via electronic mail and Federal Express:

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Washington, D.C. 20004-2402

Christopher M. Curran, Esq.
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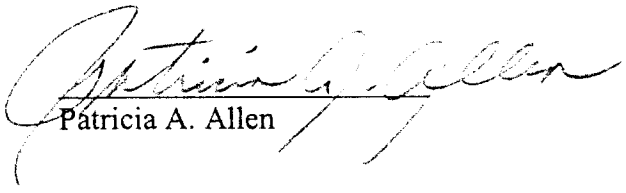

Patricia A. Allen