UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	
Schering-Plough Corporation,	)	
a corporation,	)	
	)	Docket No. 9297
Upsher-Smith Laboratories, Inc.,	)	
a corporation,	)	
	)	**PUBLIC**
and	)	
	)	
American Home Products Corporation,	)	
a corporation.	)	
	)	

UPSHER-SMITH'S MEMORANDUM ADDRESSING
COMPLAINT COUNSEL'S CITATIONS TO THE JULY 2002 FTC STUDY

In their Reply Brief, Complaint Counsel cite the Commission's Generic Drug Study (the "Study") three times. A careful examination of the Study shows that these citations do not support Complaint Counsel's arguments.

I. The Study Does Not Support Complaint Counsel's Attack On The Anti-Circumvention Clause In The Upsher-Smith Settlement

Complaint Counsel first cite the Study as showing that restraints on "noninfringing" generics "occurred only in agreements with payments." Reply Br. at 29, n.27. This reliance upon the Study is off-base in a number of ways.

First, the evidence at trial established that the Schering/Upsher-Smith settlement did not bar Upsher-Smith from marketing any "noninfringing" product. Schering's '743 patent covers sustained-release tablets formed of potassium chloride crystals that are "microencapsulate[ed]." U.S. Patent 4,863,743 at 3 (USX 713). Paragraph 3 of the Upsher-Smith Settlement Agreement (CX 348) provides that Upsher-Smith "will not market in the United States its KLOR CON® M-20 potassium chloride product, ***or any other sustained release microencapsulated potassium***

chloride tablet" (hereafter the anti-circumvention clause). This clause was narrowly tailored to restrain — for less than half the patent life — only products that Schering alleged to infringe its patent, namely "sustained release microencapsulated potassium chloride tablet[s]." This language was plainly necessary to assure Schering the benefits of settlement. If the Agreement had only restrained "Klor Con M20" by name, Upsher-Smith may have been free to circumvent the settlement by making a purely cosmetic change or by merely changing the product's name. Thus, the parties had to describe the type of product covered by the settlement. *See* Troup 5470 (Schering "wanted to make sure, I think, that I didn't rename the M20 into something else and somehow get around the language"). This type of language is essential to settle patent cases. Kerr 6334 (this clause is "the kind of language you need to have in a patent settlement."); *id.* ("if you're going to arrive at a settlement and end the patent litigation, it's essential to describe what it is the parties can and can't do"). Thus, contrary to Complaint Counsel's suggestion, the Upsher-Smith settlement does not bar "noninfringing" generic products.

Here the Commission has access to the extensive Part III adjudication record documenting the negotiating history of this clause. The final language was narrowly tailored. Cannella 3848-49; Troup 5469-70. Notably the settlement left Upsher-Smith free to market all of its then-existing products (Klor Con 8, Klor Con 10, Klor Con 20 powder, Klor Con 25 powder, Klor Con effervescent) in direct competition to Schering's K-Dur 20. And Upsher-Smith was free to develop and market any other products that did not infringe on Schering's patented "microencapsulation" tableting process.

The scope of the FTC Study does not permit any similar review of the specific drafting histories of the other settlements to which Complaint Counsel seek to refer. *See, e.g.*, Study at

A-20, A-21, App. E (Special Order). Access to the detailed negotiating history is a unique virtue of the Commission's Part III adjudication process.

Further, Complaint Counsel's expert Dr. Bresnahan who testified that he was unaware of ***any*** Upsher-Smith product blocked by this anti-circumvention clause:

> Q: Sir . . . you have been unable to identify a single Upsher-Smith product that was blocked by this language. Isn't that correct?
>
> A: That's correct.
>
> Q: And sir, you have not examined the Upsher-Smith product pipeline, have you sir?
>
> A: No.
>
> Q: And you have no evidence that Schering-Plough, as you sit here today, had any other product in mind [in the anti-circumvention clause] other than the Klor Con M20 product. Isn't that correct?
>
> A: That's right too.
>
> Q: And you have no evidence as you sit here today that Upsher-Smith had any other product in mind other than Klor Con M20. Isn't that correct?
>
> A: Yes.

Bresnahan 984.

Finally, Complaint Counsel conceded midway through trial that this clause in any event did not constitute an "independent violation" of the antitrust laws. CC Corrected Opp. To Upsher-Smith's Mot. To Dismiss (Feb. 25, 2002) at 7 n.20. Professor Bresnahan likewise concluded that the clause was not an independent violation of antitrust law, but was ancillary to the main agreement. Bresnahan 990-91.

II. The Study Findings Concerning The Average Length Of Patent Litigation Support A Ruling For Respondents

In their second reference to the Study, Complaint Counsel cite to data on the duration of patent litigation trials and appeals. Reply Br. at 37-38. Contrary to Complaint Counsel's suggestion, The Study data corroborate the witnesses at trial who testified that the Schering/Upsher-Smith settlement accelerated entry here.

A. Study Data Confirm Dr. Kerr's Conclusion That The Upsher-Smith Settlement Accelerated Generic Entry Compared To Litigation

Complaint Counsel seek to use the Study to rebut record-evidence provided by Upsher-Smith's expert William Kerr on the likely length of the Schering/Upsher patent litigation. Reply Br. at 37-38 ("His estimates are contrary to the findings of the Commission's study"). But the Study actually demonstrates the ***reasonableness*** of Dr. Kerr's litigation timing analysis.

Dr. Kerr used a decision-tree model based on patent litigation timing statistics from a broad set of hundreds of infringement cases to analyze the expected length of various litigation outcomes possible from the perspective of June 1997. Kerr 6263-64, 6938-39.[1] Accounting for the fact that a loss by Upsher-Smith would have meant no generic entry until September 5, 2006, Dr. Kerr calculated the average expected date of generic entry under continued litigation to be February 2003 — 17 months later than the Upsher-Smith settlement actually permitted. Kerr 6273.

Dr. Kerr estimated that the time from complaint to district court decision in the Schering/Upsher-Smith infringement case would be 22 months. *See* USX 1594; Kerr 6266-68.[2] The Study, on the other hand, calculates that on average first-filer litigation takes 25 months, 21 days.[3] So the average time in the Study from complaint to trial decision was ***3.7 months longer***

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[1] Dr. Kerr drew upon data from the Administrative Office of the U.S. Courts, a propreitary database of approximately 250 patent cases, and his own experience in 50 patent cases. Kerr 6243-45, 6268-70.

[2] Schering filed the M20 patent infringement complaint on December. 15, 1995. USX 677; Compl. ¶ 39. Dr. Kerr's timing analysis is from the vantage of the litigation continuing as of June 17, 1997 (18 months later) — the settlement date. The Schering/Upsher-Smith case was set for a bench trial, and Dr. Kerr's analysis conservatively assumes the district court would reach its decision 120 days thereafter, for a total of 22 months. *See* USX 1594 ("1 month" plus "90 days"), attached as Tab A.

[3] The Schering/Upsher-Smith patent case was indisputably a first-filer case. Compl. ¶ 38. Yet, in citing the Study at page 47 (Table 4-1) regarding the average length of patent litigation, Complaint Counsel did not cite the data in the column regarding the average time for cases between brand manufacturer and "First Generic Applicant." Reply Br. at 38. Instead, they chose to use data from the "Weighted Average" column, which blends in the data from "Second Generic Applicant" cases yielding a somewhat shorter time period both for the district-court and appellate-court decisions. *See* Study at 47, Table 4-1, attached as Tab B.

than Dr. Kerr's calculation. Study at 47 (Table 4-1). Thus, the Study demonstrates that Dr. Kerr's timing estimates as to the time to district court decision was actually ***conservative.***

Dr. Kerr also estimated that from the complaint to the first appellate decision in the Schering litigation would have been 41 months. USX 1599; Kerr 6268-69.[4] The Study found the average time to appellate decision for first-filer was 38 months, 27 days. Study at 47 (Table 4-1). Thus, ***Dr. Kerr's estimates were within two months of the Study's analysis, or within 5%.***[5]

Even if two months were subtracted from Dr. Kerr's overall expected date of generic entry under continued litigation, it would merely move the expected entry of Upsher-Smith under litigation forward from February 2003 to December 2002.[6] Consumers would still have experienced an acceleration of expected generic entry by 15 months compared to litigation.

Similarly, Complaint Counsel's use of the Study to attack Dr. Kerr's assumptions regarding appellate outcomes ignores the trial record. At trial, the evidence established that Upsher-Smith's chances of success were highly uncertain. The evidence also showed that Schering was a formidable litigation adversary. In light of this evidence, Dr. Kerr was reasonable to assume that Upsher-Smith and Schering each had a 50% chance of success at trial, and that there would be a 36% chance of a remand on appeal. Dr. Kerr estimated the appellate reversal and remand rates based on patent infringement case experience spanning thousands of

[4] The 41 months for first appellate decision is the sum of 22 months to decision at trial, plus 19 months. USX 1594; Kerr 6268-69.

[5] Dr. Kerr's February 2003 result is conservative insofar as it does not add in the additional delays of a petition for rehearing en banc or for certiorari at the Supreme Court, which would have further postponed the date of generic entry had litigation continued. Kerr 6275-77. Both possibilities are common, and either would have added many additional months, further delaying Upsher-Smith's ramp up and entry. Kerr 6259-60; Kralovec 5038 (Upsher-Smith would not begin ramp up until resolution of litigation). Given the purpose of the Study, it is not surprising that the Study does not present timing data on these events.

[6] Of course no trial witness, including Dr. Kerr, had access to the July 2002 FTC Study or its underlying data. Upsher-Smith sought production of these materials in its First Request for the Production of Documents, Request No. 15, dated Aug. 23, 2001, but Complaint Counsel did not produce them.

cases. Kerr 6238-39. James O'Shaughnessy, a patent lawyer with extensive patent case experience, estimated the reversal rate in infringement litigation to be 50%. O'Shaughnessy 7065-66.[7]

Complaint Counsel elected not to present an expert witness to reanalyze Dr. Kerr's work or to generate its own patent litigation timing model. The Study data supports Dr. Kerr's work — the ***only*** timing model presented and defended at trial.

B. The Study Does Not Refute the Litigation Timing Testimony of Complaint Counsel's Expert Adelman Demonstrating the *Acceleration* of Entry Under the Upsher-Smith Settlement

The problem for Upsher-Smith was that it also had to consider not just the average litigation time to a final decision before it could enter, but the cold hard reality that the resolution of litigation could take much longer. This was well-known to experts in patent settlements, such as Dr. Kerr. Like Dr. Kerr, Complaint Counsel's expert Professor Martin Adelman, based his testimony on his experience with general patent infringement cases (Adelman 7703), not just ANDA cases.

Professor Adelman's testimony regarding the potential length of patent litigation supported the procompetitive effects of the Upsher-Smith settlement. Professor Adelman testified that in simple patent cases district courts can take up to five years to decide the case. Adelman 7772-73. Beyond the district court, Professor Adelman further testified that appeals in

[7] Data concerning the delay associated with Paragraph IV ANDA cases continue to develop, even after the Study's June 1, 2002 cutoff date. A substantial portion of all of the Paragraph IV ANDA cases in the Study were not completed as of the cutoff date. Study at 16 (22 of the 75 drug products cases pending at cutoff). The Study profiled the litigation concerning Paxil, a branded drug with more than $1 billion in sales. Study at 49 (Table 4-1), 52 (Figure 4-1). In December 2002, the district court in the *Paxil* patent-infringement case, ***after four years***, granted a summary judgment ruling ***against*** the generic firm. "Update on Paxil Litigation," GlaxoSmithKline Press Release, Dec. 30, 2002 at 1 (E.D. Pa. ruling against TorPharm's generic), attached at Tab C. Like the K-Dur 20 patent, the Paxil patents expire in 2006. *Id*. But unlike K-Dur 20, where consumers had a settlement that permitted two generic drugs to enter in September 2001, consumers have no current prospects of a generic drug for Paxil, as of January 2003. Should the Commission ultimately take official notice of these Study conclusions, it should also take official notice of the delay and outcome of the *Paxil* case.

the Federal Circuit can take as long as an additional three years, or even longer. Adelman 7774. This would have been two years ***later*** than the September 1, 2001 entry date. By contrast, the Study does not present data on the longest patent cases in its sample. And, again, Upsher-Smith lacks access to the underlying Study data.

The Study also does not purport to answer the fact-specific question of the lengthy delay that the M20 Upsher-Smith infringement case might have faced in the U.S. Court of Appeals for the Federal Circuit.[8] Unlike the settlements reported in the Study, Professor Adelman testified that due to the specific patent issues raised in the Schering M20 infringement case against Upsher, the Federal Circuit decision might well have been held up until the U.S. Supreme Court decided the *Festo* decision. Adelman 7776 ("it could have been delayed until Festo, and I suppose you could delay it until the Supreme Court's deciding Festo"). *Festo* was pending when Adelman testified on March 14, 2002 (Adelman 7778). The U.S. Supreme Court did not hand down the *Festo* decision until May 28, 2002[9] — 9 months ***after*** consumers got the benefit of Upsher-Smith's entry occurred under the settlement.

Of course, even beyond the end of all infringement litigation, Upsher-Smith needed an additional 27 months to build onto its factory in order to accomplish the massive, low-cost 100-million tablet launch that it did make on September 1, 2001 (UPF 712).[10]

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[8] Nor was the Study intended to describe litigation expectations as of June 1997, the relevant time period according to Complaint Counsel's experts Bazerman and Bresnahan. The Study presents a snapshot of Paragraph IV ANDA case outcomes as of its cutoff date some five years later — June 1, 2002. Study at 16.

[9] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki, Co.*, 535 U.S. 722, 122 S.Ct. 1831 (May 28, 2002). The *Festo* case deals with the doctrine of equivalents. Given the Study's focus, it is not surprising that the Study does not indicate which, if any, of the other patent settlements presented a *Festo* issue that could have impacted timing.

Festo is instructive as to how long a patent infringement case can take. The case has already lasted more than 10 years. *Festo*, 1994 WL 1743984 (D. Mass., Feb. 3, 1994) (discussing report of Special Master, assigned to the matter in May, 1992), and has been remanded for further action. 122 S.Ct. at 1843.

[10] Unlike the Study, for this settlement the Commission has the actual context of the settlement talks here: Upsher-Smith initiated them after its expert (Banker) had abandoned it; Troup was concerned about the outcome and expense of litigation; the district judge had not ruled on the summary judgment motion; the judge had denied the lifting of the 30-month stay. UR-CPF 85-165.

III. The Study Does Not Demonstrate That A Competition Ruling Against "Brand Payments" For Fair Value Would be Sound Public Policy

Finally, Complaint Counsel in their Reply Brief cite the Study for the proposition that "while publicity has put an end to settlements with payments, settlements of Paragraph IV cases have continued." CC Reply Br. 46 (citing Study at vii-viii, 27). In fact, the Study says nothing of the sort. And more fundamentally, the Schering/Upsher-Smith settlement cannot fairly be characterized as a "settlement with [a] payment[]." The Study does not shed light on so-called "reverse payments in the context found here." Reply Br. at 46.

A. Study Only Examines Publicity About Interim Settlements

At pages vii-viii, the Study states unequivocally that publicity of FTC enforcement proceedings has put an end to "***interim agreements***," such as those in the *Hoechst/Andrx* and *Abbott/Geneva* cases. Because the Upsher-Smith settlement is a ***final settlement***, Complaint Counsel were forced to concede that they "erroneously" cited to pages vii-viii of the Study in their Reply Brief. CC Opp. To Mot. To Strike Reliance on Study at 5, n.9 (Dec. 9, 2002). Furthermore, the Study unequivocally does ***not*** state that publicity has put an end to "settlements with payments," nor does the Report comment on how ending "settlements with payments" or "settlements with side deals" would affect the frequency of final settlements.

Complaint Counsel's recent Opposition cannot salvage the argument by arguing that "the majority of the settlements (six of nine) involving licenses or supply agreements occurred in 2000 and 2001." Opp. at 5 (citing Study at 27-31). Nowhere in the Study's treatment at page 27 of the settlements entered in "2000 and 2001" does it address the effects of publicity. Indeed, given that this proceeding was first publicized on April 2, 2001, and the Study gathers information only until June 1, 2002, the Study could hardly have commented authoritatively on

the effect of publicity of this action. There is no indication how many settlements have occurred since April 2, 2001 — of any structure.[11]

B. Brand Payments For Fair Value Were Not Challenged

Complaint Counsel declared at the outset of the trial that "[t]his case does not challenge the settlement of patent disputes by an agreement on a date of entry, standing alone, or the payment of fair market value in connection with 'side deals' to such an agreement." CC PreTrial Br. at 43; ID at 107. Similarly, Dr. Bresnahan testified that "had Upsher-Smith and Schering-Plough entered into an agreement that contained a side deal at fair value" that "would not be anticompetitive." Bresnahan 932-33 (quoted at ID at 107). Bresnahan testified that "if Schering-Plough had made a stand-alone determination that it was getting as much in return from those products as it was paying, then I would infer that they were not paying for delay." Bresnahan 964-65 (quoted at IDF 172). Valuation must be assessed from the perspective of the brand company and measured at the time of the side-deal, here June 1997. Bresnahan 964-65 (each prong of Bresnahan Test, including the valuation prong, measured at June 1997). Certainly the Study does not suggest that a settlement for fair value would be anticompetitive.

C. Fair Value Was Proven In The Context Of The Upsher-Smith Settlement

The Upsher-Smith settlement is unique among settlements involving "brand payments" discussed in this portion of the Study, because it is the only one documented as involving a side deal with "fees for licenses to other products." Study at 33, Table 3-3, Settlement L. None of the other settlements are reported to involve a license payment with a side license. Study at 32. Apparently, the other Table 3-3 settlements contain naked "brand payments." *See* Table 3-3.

[11] This argument also ignores that of the Study's twenty final settlements involving first generic applicants, nine — almost half — included a brand payment, indicating the widespread use of brand payments to settle cases. Study at 25.

The Commission also has here, unlike the settlements in the Study, both the subjective and objective valuation evidence that the brand payments were supported by six product licenses and six supply agreements granted by Upsher-Smith — there was no ***net*** brand payment. From Schering's subjective standpoint, in June 1997 Schering's James Audibert projected annual sales for Niacor-SR reaching $149 million (ID 108; SPX 2) and that Schering calculated the value of the licenses for Niacor-SR and the other products at $225 to $265 million, net of the $60 million in upfront royalties. SPX 26 at 1600275. Even before Upsher-Smith offered Schering the Niacor-SR license Schering had projected sales for Kos' Niaspan of $134 million in 2002 rising to $193 million— sales comparable to Audibert's projections for Niacor-SR.[12] Russo 3461, 3529; CX 550 at SP 002743; *see* IDFs 256-57, 259 ("None of Complaint Counsel's witnesses challenged Schering's calculation…"); Bresnahan 975-76 (Bresnahan does not challenge the Schering Board valuation numbers). Schering's Board reviewed and authorized the licensing agreement in June of 1997. CX 340.

Using an objective standard for valuation, unlike any other settlement listed in the Study, the record evidence here is that Schering received fair value for the brand payment from the six Upsher-Smith drug licenses and six manufacturing agreements.[13] Contemporaneous with and discussed during the Niacor-SR negotiations, the stock market corroborated the parties'

[12] The Schering June 9, 1997 memo detailing why Schering did not conclude and agreement to co-market Kos's Niaspan is not to the contrary. CX 558. The memo underscores that the Niaspan co-marketing arrangement was not rich enough because it gave Schering at most only 50% of the expected sales and came at the additional cost of meeting Kos's "irrational" demands regarding detailing priority over Claritin and the booking of sales. CX 558. *See also* SPF 1.118, 1.390-92, 1.152, 1.157 (detailing Kos demands); ID at 110 (holding "The substantial, reliable evidence demonstrates legitimate credible reasons for Schering's preference of a licensing deal with Upsher-Smith over a co-marketing arrangement with Kos. F. 217-219.").

[13] Expert trial testimony confirmed that Schering could have paid up to $100 million for the Niacor-SR license alone. Horovitz 3607-13, 3618; IDF 260. Kerr's sensitivity analysis demonstrated that making highly conservative adjustments in the Audibert valuation model still yield a net value of more than $100 million to Schering, as of June 1997. Kerr 6287-90; USX 1602, attached as Tab D. Expert testimony established that the five other Upsher-Smith products licensed to Schering had an economic value to Schering of $10.1 million. Kerr 6301-02; UPF 458. None of Complaint Counsel's experts performed a contrary NPV analysis.

assessment of the value of the licenses; by June of 1997 Kos's market capitalization had soared to approximately $400 million on the strength of expected Niaspan sales. USX 1026; USX 535 at 11515; SPX 225 at 2; *see* IDF 187-92.

D. Complaint Counsel's References to "Brand Payments" and "Patent Licenses" Ignore the Study's Findings, the Patent-Shortening Licenses Here, and the Absence of Any Assessment of Procompetitive Effects in the Study

In seeking to use the Study to bolster its case for a "rule of law" Complaint Counsel seek, the Reply Brief attempts to distinguish between "settlements with payments" and other "settlements of Paragraph IV cases." Reply Br. at 46 (citing Study at 27 and 31). In expanding the citation from page 27 and 31 to the four pages 27-31 of the Study, Complaint Counsel's Opposition (Opp. at 5, nn.8, 9) directs the Commission's attention to the section of the Study discussing final settlements "involving patent licenses" on the one hand (listed in Table 3-2, Study at 29) and settlements "involving brand payments" on the other. Study at 31 (listed in Table 3-3, Study at 32). Complaint Counsel's purported reliance on the two categories of settlements ignores the actual, fact-specific findings of the Study, as well as the specific Part III hearing evidence here.

1. Upsher-Smith Received Patent-Shortening Licenses That Permitted Better-Than-Midpoint Entry During the Remainder of the '743 Patent

The Upsher-Smith settlement involved Schering granting Upsher-Smith a license to sell its M20 product starting on September 1, 2001 (CX 348 at ¶3), cutting 5 years off the life of the '743 patent. IDF 157, 386. The midpoint date is February 2002, measured from June 1997; the settlement is better for consumers than the midpoint. See Tab E (USX 1011); Bresnahan 894 (admitting Upsher settlement is 5 months better for consumers than midpoint of remaining patent life, February 2002). The 5 years removed is more than 54% of the remaining life of the patent

in June 1997. Bresnahan 895. Upsher-Smith had no FDA-approved product in June 1997; FDA approval came in November 1998. UR-CPF 165. Measured from FDA approval, the Upsher-Smith settlement removed about two-thirds — 64% — of the remaining life of the patent. UR-CPF 165.

Thus, the Part III proceedings revealed that the Upsher-Smith settlement has much in common with the other settlements that involve licenses in Table 3-2. This patent-shortening aspect of the Upsher settlement compares favorably with the "license" settlements in Table 3-2 of the Study. Half of the settlements involving patent licenses (Table 3-2) do not involve immediate entry by the generic, but involve entry some time after the settlement date. Study at 29 (Table 3-2 (drugs A, E, F, and H)) attached as Tab F. And the Upsher settlement, by taking off more than half of the remaining life of the patent, removes a greater percentage of the remaining life of the patent than two of these four settlements, including the settlement involving the biggest selling branded drug. Study at 29 (Table 3-2 (drug E: 50% off remaining patent life; drug H: less than half of remaining life off)).

Moreover, the patent-shortening effect of the Upsher settlement comes without the additional costs of a royalty, as the Study reveals. The Upsher-Smith settlement provided Upsher-Smith with a royalty-free license from Schering to sell Upsher's own generic version of K-Dur 20. Settlement ¶3 (CX 348). By contrast, six of the eight license agreements required the generic firm to pay a royalty to the branded firm — in one case a royalty as high as 60%. Study at 31 (Table 3-2). Consumers benefited from the royalty-free license Upsher-Smith obtained, because its costs were lower than if it had to recoup a royalty by charging higher prices.

The five-year patent-shortening of the Settlement further distinguishes the Upsher settlement from the Table 3-3 brand payment settlements. From the face of the report, Upsher's

settlement appears to be the ***only*** settlement contained in Table 3-3 to have removed more than half of the remaining life of the patent. In fact, for all but one other settlement in that Table, the agreements with brand payments prohibited generic until the end of the life of the patent — a timing effect far removed from the Upsher-Smith patent, which expires on September 5, 2006. *Study* at 31 (noting that six of the eight settlements appearing in Table 3-3 prohibited the generic entering "until the expiration of the patents").[14]

2. The Study Does not Assess Procompetitive Effects of the Various Settlements

Given its scope, the Study is understandably silent as to the existence of any actual procompetitive benefits of the settlements with "brand payments." Study at 31. Nowhere does the Study conclude that all of the settlements involving "brand payments" are settlements truly involving "reverse payments" as Complaint Counsel assert in their Reply Brief (at 46), or that the "brand payment" settlements are ultimately net anticompetitive.

The Study does not provide any basis to support Complaint Counsel's argument that prohibiting settlements "in the context found here" — the Upsher-Smith settlement context — would not prevent generic firms from pursuing procompetitive settlements. The Part III trial revealed that the Upsher-Smith settlement yielded numerous procompetitive benefits.

The Settlement had the unique procompetitive benefit of liberating a second drug from potential litigation — Klor-Con M10, the second drug Schering licensed in shortening its patent. CX 348 at ¶3. A settlement without M10 could have led to a second, entry-delaying lawsuit. Kerr 6253, 6335-36; Troup 5471-2. Instead, Upsher-Smith through the settlement cleared the

[14] In a footnote, Table 3-3 the Study indicates two settlements, the Upsher-Smith Settlement ("Drug Product L") and "Drug Product O" permitted generic entry "prior to patent expiration pursuant to a license." Study at 32. Upsher-Smith has no information regarding the details or Drug Product O and therefore cannot properly address whether that settlement was comparable to the Upsher-Smith Settlement (i.e., whether it was a better-than-midpoint settlement for consumers).

way to bring M10 to consumers as part of its massive September 2001 Klor Con launch. Not one of the other 20 settlements in the Study (pp.27-31) indicate that a second generic drug was accelerated via a second license.

The Upsher-Smith settlement permitted new production investment of $20 million (UPF 713), which more than doubled Upsher-Smith's potassium output (UPF 717, 722-734; Gould 5129-30; Kralovec 5047-49). Upsher-Smith was only able to carry out the massive September 2001 100 million tablet launch of M20 and M10 due to the settlement. Troup 5483-85; Kralovec 5038-39; Gould 5136. This new production investment cut Upsher-Smith's production costs for Klor-Con M in half. USX 509 (batch cost dropping from $14.45 to $6.30 per kg), attached at Tab G; CX 622 at 504 (predicting annual savings of $500,000); USX 289. No similar effects are shown for any other settlement in the Study, be it listed in Table 3-2 or 3-3.

Further, the settlement saved Upsher-Smith its litigation costs, which totaled over $3 million (UPF 833; Kralovec 5035; Canella 3818-24) — a sum that represented almost 10% of Upsher's total 1996 sales. UPF 4 (1996 sales of $35 million). The settlement permitted more expenditure of marketing against K-Dur 20. Dritsas 4894-95; Kralovec 5037, Dritsas 4663-64; *see also* Bresnahan 909-10 (litigation drains money from marketing and research). Such specific impact of the opportunity costs of litigation are beyond the scope of the Study (pp. 27-31), as are the other procompetitive benefits demonstrated at trial, such as a return on its $17 million investment in drug development; expanded distribution for Upsher's licensed products; permitted Upsher-Smith to license Qualitest to make an additional generic to K-Dur available to consumers; and saved the limited resources of the parties and the courts. *See* Upsher App. Br. at 42-44. These procompetitive benefits are why Part III adjudications cannot be short-cut by mere reference to the Study.

CONCLUSION

Complaint Counsel misapply the Study and ignore the substantial support the Study provides for a ruling on behalf of Upsher-Smith.

January 27, 2003

Respectfully submitted,

WHITE & CASE LLP

By:_____

Robert D. Paul
J. Mark Gidley
Christopher M. Curran
601 Thirteenth Street, N.W.
Washington, D.C. 20005-3807
Telephone: (202) 626-3600
Facsimile: (202) 639-9355

Attorneys for Upsher-Smith Laboratories, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on January 27, 2003, I caused a paper original, an electronic copy, and twelve paper copies of UPSHER-SMITH'S MEMORANDUM ADDRESSING COMPLAINT COUNSEL'S CITATIONS TO THE JULY 2002 FTC STUDY to be filed with the Secretary of the Commission:

Office of the Secretary
Federal Trade Commission, Room 104
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

and one copy to be served by hand delivery upon:

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Ave, N.W.
Washington, D.C. 20580

and one paper copy to be hand-delivered upon the following counsel:

David R. Pender
Assistant Director
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Counsel Supporting the Complaint

Laura S. Shores
Howrey Simon Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, DC 20004

Counsel for Schering-Plough Corporation

Michael B. Kades
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Counsel Supporting the Complaint

Marcus H. Meier
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Counsel Supporting the Complaint

_____
Robert K. Williams

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