UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: Timothy J. Muris, Chairman
Sheila F. Anthony
Mozelle W. Thompson
Orson Swindle
Thomas B. Leary

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

COMPLAINT COUNSEL'S OPPOSITION TO UPSHER'S MEMORANDUM ON THE COMMISSION'S *GENERIC DRUG STUDY*

The Commission provided Upsher an opportunity to disprove certain findings from the Commission's recent study, *Generic Drug Entry Prior to Patent Expiration* (July 2002). Upsher, however, has offered nothing to undermine the reliability of the Study's findings. Instead, it has used the Commission's invitation as an excuse to file a post-oral-argument sur-reply brief. We respond because, in addition to repeating its prior arguments on the merits, Upsher makes various new and incorrect assertions concerning matters of adjudicative fact.

I. The Study's Finding that Hatch-Waxman Cases Can Be, and Increasingly Are, Settled Without Brand Payments Is Unchallenged

Upsher does not dispute the Study's findings that: (1) settlements of Paragraph IV litigation occurred without payments from the branded drug maker to the allegedly infringing generic applicant

(what the Study terms "brand payments") (Study at 27-31); and (2) the bulk of the settlements without brand payments occurred in 2000 and 2001 (*id.* at 27), i.e., after the Commission's investigations in this area had become public (*id.* at 34). Further, Upsher does not dispute the policy implication of these findings: that brand payments are not necessary to settle patent infringement cases in the pharmaceutical industry.

Instead, Upsher launches into arguments concerning matters of adjudicative fact in this proceeding. Upsher not only argues it was not paid to settle, but also offers its spin on an internal Schering memorandum that complaint counsel used at oral argument (CX 558, Mr. Driscoll's June 9, 1997 memo discussing Schering's decision not to pursue Niaspan), and even purports to quote language that does not appear in the document. *See* Mem. at 10 n.12.

Upsher also devotes considerable space to what it terms the "unique procompetitive benefits" of its settlement with Schering. While much is repeated from its answering brief, Upsher now claims that the settlement "permitted new production investment of $20 million" – *double* what it previously told the Commission (s*ee* UAB at 39-40)[1] – and also says that this investment "cut Upsher-Smith's production costs for Klor Con M in half" (an assertion that is both new and not substantiated by the documents Upsher cites).[2] Mem. at 14. Moreover, the claim that the settlement "permitted" such

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[1] This change appears to reflect a new characterization of inventory costs as cost-cutting new production investment. *See* Mem. at 14, citing UPF 713 (discussing $10 million in new production investment and $10-11 million in inventory costs).

[2] Upsher's own prior statement contradicts the claim based on USX 509. This document contains August 1999 estimates (not actual figures) of batch costs (not total production costs). The $6.30 per kg. estimate that Upsher takes from USX 509 is based on a batch size of 712 kg., but Upsher has said elsewhere that it used a 400 kg. batch size for the 2001 launch. *See* UPF 763; *see*

(continued...)

investment does not provide a justification for Upsher's demanding and receiving a payment to accept the settlement.

First, Upsher does not and cannot claim that it needed up-front payments from Schering to pay for production investments, or that it was otherwise short of cash at the time of the settlement. The record evidence shows that those payments were passed on to its shareholders.[3] In addition, Upsher specifically disclaimed any such defense based on its financial condition, in order to avoid turning over certain financial records.[4]

Second, a claim that the certain entry date, rather than Schering's payments, "permitted" the investment cannot justify the payment not to compete, because Upsher could have settled for a certain entry date without a payment. In other words, Schering's payments were not reasonably necessary to the asserted goal of achieving a settlement with a fixed entry date. That Upsher would not agree to the September 2001 entry date Schering proposed without a payment merely means that Upsher thought that absent the payment it would be better off continuing to litigate. Finally, Upsher's post-hoc claims

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[2](...continued)
also Tr. 21:5149-50 (Gould) (Upsher got FDA approval for 400 kg. batch size in May 2000). The other two documents cited, CX 622 at Upsher-Smith FTC 088504 [in camera] and USX 289 [in camera], also contain ••••••••••••••••••••••••••••••••••••, and Upsher likewise offers no evidence that it achieved the •••••••••••••••••• outlined in these documents.

[3] *See* CPF 1318-25; Tr. 23:5594 (Troup) (the $60 million Schering paid Upsher was passed through to Upsher's shareholders); Tr. 21:5066-67 (Kralovec) (Upsher distributed to shareholders at least as much as it received from Schering in each of the three years that it received installments on the $60 million); *see also* CX 317 at USL 01642 (Upsher Financial Statements) [in camera].

[4] *See* Letter from Rajeev K. Malik, White & Case, to Yaa A. Apori, Federal Trade Commission (August 28, 2001) at 2-3 (attached at Tab A) (stating Upsher would not "raise a defense that uses Upsher-Smith's financial condition as a justification for entering into the licensing agreement with Schering-Plough").

that it could not have launched before September 2001, or could not have launched on a scale that would have benefitted consumers, are implausible in light of contemporaneous documents. *See* CCARB at 37-39; CCPTRB at 34; CPF 141-160.

II. The Study's Finding That Restraints on Non-Infringing Products Occurred in Settlements Involving Brand Payments to the Allegedly Infringing Generic Applicant, But Not Other Settlements, Is Unrefuted

Upsher does not challenge the Study's findings that provisions restricting the ability of the alleged infringer to market *any* generic equivalent version of the brand name drug product arose in settlements involving brand payments, but did not occur in numerous other settlements. Study at 30, 31. In addition, while it makes passing reference to its economist's opinion that such provisions are essential to settlement, Upsher does not seriously dispute the obvious implication of the Study's findings on collateral restraints, i.e., that such provisions are not necessary to settle pharmaceutical patent litigation. Whether or not Schering believed such a provision was essential to achieve the anticompetitive effects of its settlement with Upsher, the Study shows Hatch-Waxman settlements generally have not contained one.[5]

Once again, rather than deal with the Study, Upsher offers new (and incorrect) assertions concerning matters of adjudicative fact. Here, the settlement language bars Upsher from selling its ANDA product and "any other sustained release microencapsulated potassium chloride tablet" (CX

[5] Contrary to Upsher's assertion, we did not state that the provision in the Schering/Upsher settlement barring sale of any generic version of K-Dur 20 did not amount to an independent violation of law. Rather, we pointed out that the Commission's complaint in this case did not plead it as an independent violation. *See* Complaint Counsel's Opposition to Upsher-Smith's Motion to Dismiss (February 25, 2002) at 7 n.20.

348 at USL 03186). According to Upsher, that language does not prohibit the sale of non-infringing products, because "Schering's '743 patent covers sustained-release tablets formed of potassium chloride crystals that are 'microencapsulat[ed]'" (Mem. at 1), and the provision was limited to "only products that Schering alleged to infringe its patent, namely 'sustained release microencapsulated potassium chloride tablet[s].'" Mem. at 2.

In fact, Schering – the patent holder – has not claimed that *any* sustained release microencapsulated potassium chloride product would infringe its patent.[6] Schering's '743 patent claims a controlled-release potassium chloride tablet containing potassium chloride crystals that are coated with a specified coating material (one that includes a mixture of ethylcellulose with a specified viscosity, along with hydroxypropylcellulose and/or polyethelene glycol).[7] Upsher – the alleged infringer – now takes a far broader view of Schering's patent than either party did in the underlying patent litigation. This latest twist is just one more example of how Upsher's positions in this antitrust suit differ from the

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[6] The pleadings in the patent case (which were admitted to show the positions taken by the parties in the underlying litigation) show that Schering alleged only that those microencapsulated potassium chloride tablets having a coating that falls within the literal limits of the patent claim, or that is "insubstantially different" from the claimed coating, infringe its patent. *See, e.g.*, SPX 683 at USL PLD 002443-456 (Memorandum of Key Pharmaceuticals, Inc. in Opposition to Upsher-Smith's Motion for Summary Judgment of Non-Infringement at 12-25); *see also* Respondent Schering-Plough Corporation's Objections and Responses to Complaint Counsel's Revised Second Request for Admissions (Nov. 14, 2001) at 7. In addition, Schering did not sue Andrx for patent infringement after Andrx filed a Paragraph IV certification for a generic version of K-Dur 20. CPF 73.

[7] CX 12 (the '743 patent) at FTC 0021322-23; CPF 102; *see also* Complaint Counsel's Reply to Schering's Discussion of the Merits of the Underlying Patent Litigations, Appendix to Complaint Counsel's Post Trial Reply Brief (April 26, 2002) at A-11.

views it expressed during the patent infringement case.[8]

III. The Study's Data on Average Length of Hatch-Waxman Litigation Do Not Advance Upsher's Defense

After accusing complaint counsel of improperly using the Study to prove adjudicative facts, Upsher now endeavors to do precisely that. Rather than disputing the Study's findings on the average length of Hatch-Waxman patent litigation, Upsher embraces these findings and argues that they support its own expert's analysis that the settlement did not delay entry. Of course, even accepting Dr. Kerr's figures on average length of patent litigation, the case (which began in December 1995) would have reached a district court decision by October 1997, and an appellate decision by May 1999 – over two years earlier than the September 2001 entry date under the settlement. Dr. Kerr arrives at an expected entry date of February 2003 only by assuming that Upsher had a 50% chance of losing the suit (and thus being barred from entry until the patent expired in 2006).

We referred to Study's findings on average length of litigation solely when pointing out that Upsher's effort to use a statement by Professor Adelman to support its claims concerning the likely length of the patent case was misplaced. CCARB at 38. We have never contended that these Study data show the likely length of the Schering/Upsher patent litigation, had it been litigated to a conclusion. Many variables can affect the duration of litigation in individual cases, including, for example, the number of patents at issue in the case and the timing of Orange Book

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[8] Although Upsher claims that it initiated settlement talks in May 1997 "after its expert (Banker) had abandoned it" (Mem. at 7 n.10), in fact Upsher had never retained Dr. Banker for the litigation. *See* Tr. 22:5204-05 (Banker) (Upsher sought to retain him in late 1995 and he declined).

listings.[9] As a result, contrary to Upsher's claims, industry averages (whether those of Dr. Kerr or the Study data on Hatch-Waxman cases) do not advance Upsher's defense.

Moreover, all sides in this antitrust case agree that the Commission should evaluate the agreement as of the time it was entered into. The parties' contemporaneous business documents show that just prior to the settlement agreement both were anticipating generic entry by Upsher well before September 2001. CPF 74-82; 118-162. More fundamentally, these documents confirm what is obvious from the settlement itself: both Schering and Upsher thought entry by Upsher before September 2001 was sufficiently likely that Schering was willing to pay, and Upsher to insist upon, $60 million to settle the suit. Upsher's various contentions are merely an effort to divert attention from this fundamental point.

Although the Study's findings concerning the average length of litigation do not show when Upsher was prepared to enter, they do have policy implications for this case. The data on average length of patent litigation – which show an average of slightly over two years from complaint to district court decision and slightly more than three years from complaint to appellate decision – mean that a victory by the generic applicant can occur well before patent expiration. Thus, a settlement may delay competition even when it does not bar entry until patent expiration. Therefore, it is wrong to presume (as respondents do) that a patent settlement with an entry date prior to patent expiration is "patent-

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[9] For example, the December 2002 decision concerning Paxil to which Upsher refers (Mem. at 6 n.7) involves a series of four patents that resulted in infringement charges brought in August 1999, September 2000, January 2001, and May 2001. *See SmithKline Beecham Corp. v. Geneva Pharms., Inc*., 2002 U.S. Dist. LEXIS 25275 (E.D. Pa. Dec. 20, 2002). Upsher's statement that these patents expire in 2006 is based on its misreading of the GSK press release that it submitted to the Commission.

shortening." That characterization would be accurate only if one assumes that Upsher's ANDA product infringed Schering's patent – an assumption that has no basis in law or this record.

Conclusion

Upsher has offered nothing to disprove the accuracy or reliability of the Study's findings. The Commission may, therefore, consistent with its Rules of Practice, 16 C.F.R. § 3.43(d) (2002), properly rely on the cited Study findings in addressing matters of policy.

Respectfully submitted,

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Attachment