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,	)	
	)	
and	)	
	)	
American Home Products Corporation,	)	
a corporation.	)	
	)	

UPSHER-SMITH'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO STRIKE COMPLAINT COUNSEL'S RELIANCE ON THE JULY 2002 FTC STUDY

As explained below, Complaint Counsel's opposition fails to justify why a study prepared in part by themselves and published ***after*** the close of the record ought to be considered against Upsher-Smith:

1. Complaint Counsel concede the FTC Study they cite in their appellate reply brief falls outside the record. *See* Opp. at 2 (stating that the FTC Study "is not record evidence"); *id.* (describing the FTC Study as "extra-record information").

2. Complaint Counsel do not discuss, much less dispute, the cases holding that tribunals may not consider non-record evidence raised for the first time on appeal — even when the new information consists of Government or scientific studies. *See United States v. Bines*, Nos. 94-50082, 94-50212, 94-50382, 1995 WL 490152, *7 n.3 (9th Cir. Aug. 15, 1995) (rejecting consideration of non-record study on race-based prosecutions); *United States v Bonds*, 12 F.3d 540 (6th Cir. 1993) (rejecting consideration of non-record scientific study); *Carley v. Wheeled*

Coach, 991 F.2d 1117, 1126 (3d Cir. 1993) (rejecting consideration of non-record Government study); *In the Matter of Litton Industries*, 97 F.T.C. 1, 54-55 ((1981) (ALJ rejecting consideration of non-record study).

3. Complaint Counsel also make no effort to reconcile their reliance on the FTC Study with the Commission's September 27, 2002 Order ("Order") granting Upsher-Smith's motion to strike Complaint Counsel's non-record demonstrative exhibits. There, the Commission held that "ascertaining the validity of Complaint Counsel's analysis and the underlying data is a function . . . more appropriately undertaken within the bounds of the administrative trial." Order at 3. Indeed, many legal scholars have endorsed the Commission's sound approach. *See, e.g.*, John Frazier Jackson, *The Brandies Brief—Too Little, Too Late: The Trial Court as a Superior Forum for Presenting Legislative Facts*, 17 Am. J. Trial Advoc.1, 5 (1993) ("[F]acts are tested most effectively in the trial arena through the tools of observation and cross-examination. Litigants can use these tools to analyze the accuracy of the evidence and the sincerity, honesty, and competency of those presenting it."); *see also* Ellie Margolis, *Beyond Brandeis: Exploring the Uses of Non-Legal Materials in Appellate Briefs*, 34 U.S.F.L. Rev. 197, 217-18 (2000) (authority cited by Complaint Counsel acknowledging the views of many legal scholars that trial is the superior forum for introducing information and that "[p]roviding information through a brief is a second-best solution, to be employed primarily by appellate lawyers stuck with an inadequate trial record.").

4. Complaint Counsel also do not dispute that the Study is inappropriate for judicial or official notice. *See* Opp. at 3-4 (Complaint Counsel arguing that Upsher-Smith's cases on judicial notice are "irrelevant"). Consequently, Complaint Counsel do not urge the Commission to take judicial or official notice of the Study.

5. Realizing they may not rely on non-record evidence and that judicial or official notice of the Study is inappropriate, Complaint Counsel contend — without pointing to any applicable rule — that the Study "can and should be used to inform the legal and policy considerations of the Commission's decisions." Opp. at 2. By their own admission, however, Complaint Counsel rely on the Study to "contradict claims" established at trial. *See* Opp. at 1, 4-6 (detailing specific record facts Complaint Counsel seeks to disprove). Specifically, Complaint Counsel try to use the FTC Study to rebut the testimony of Dr. William Kerr, who performed an analysis of the expected entry date for Upsher-Smith's Klor-Con M20 product under a litigation scenario. Although Complaint Counsel fully exploited their opportunity to test Dr. Kerr's analysis through pre-trial discovery and cross-examination at trial, Complaint Counsel missed the November 15, 2001 deadline to advance rebuttal expert testimony and chose not to rebut this aspect of Dr. Kerr's testimony at trial. Thus, Complaint Counsel now rely on the Study to do precisely what they concede they may not — "establish facts needed to prove a violation of law."

6. While Complaint Counsel argue that the Study simply presents "legislative facts," seemingly immune from the rules of evidence or the adversarial process, Complaint Counsel provide no reason beyond their own *ipsi dixit* to support this contention. Many tribunals, however, including the Commission, have acknowledged that legislative facts are matters of common knowledge, or at least matters that are capable of certain and accurate verification. *See, e.g., Gebremichael v. INS*, 10 F.3d 28, 37 (1st Cir. 1993) (holding Board of Immigration Appeals may consider legislative facts, including "a change in government in an applicant's home country"); *Kaczmarczyk v. INS*, 933 F.2d 588, 593-94 (7th Cir. 1991) (affirming agency's decision to consider notice of Poland's changed political circumstances); *Greci v. Birknes*, 527 F.2d 956, 959 n.4 (1st Cir. 1976) (considering legislative history of extradition treaty as

authoritative legislative facts); *United States v. Gould,* 536 F.2d at 220 (holding fact that substance is a schedule II drug as defined by statute is a legislative fact). In *In re Manco Watch Strap Co.,* 60 F.T.C. 495 (1962) (Commission considering legislative fact because "of the frequency and consistency with which proof of the existence of such [fact] has been shown in countless prior proceedings."). Unlike those cases, the facts proffered by the FTC Study are not a matter of common knowledge, capable of certain and accurate verification or proven in "countless proceedings."

7. Notably, Complaint Counsel do not dispute that they misstated the Study's findings by citing to the Study's discussion of ***Interim Agreements***, while the settlement between Upsher-Smith and Schering was a ***Final Settlement***. Mem. at 7-8. Instead, Complaint Counsel ***again*** misstate the Study's findings by suggesting that the Study — which they helped draft — labeled the settlement between Upsher-Smith and Schering a "reverse payment." Opp. at 5 n.8. The Study, however, never uses the pejorative term "reverse payment" — a label that presumes there was a payment for delay, not a payment for a license. Rather, the Study utilizes the more neutral term "brand payment." *See* Study at 31-32.

8. Moreover, due to the Study's ambiguous and incomplete descriptions of anonymous settlements, neither Upsher-Smith nor a policy-maker can compare Upsher-Smith's settlement to any of the other 19 settlements mentioned in the Study. Indeed, the Study presents no facts about whether other brand payments were for licenses, much less the full factual backgrounds of those settlements.

9. Complaint Counsel declare that "it would be irresponsible for complaint counsel to fail to reference those portions of the study that could assist the Commission in its thinking

about the legal and policy issues raised in this case." Oddly, however, Complaint Counsel chose to wait until its appellate reply brief to rely on the FTC Study.

10. In light of Complaint Counsel's concessions that the Study falls outside the record and is inappropriate for judicial or official notice, the Commission should strike Complaint Counsel's reliance on the FTC Study.

December 16, 2002

Respectfully submitted,

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