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 MOTION TO STRIKE
COMPLAINT COUNSEL'S RELIANCE ON THE JULY 2002 FTC STUDY

In their Reply Brief, Complaint Counsel three times refer to an FTC study entitled *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002). Complaint Counsel cite the Study as the basis for factual contentions that were never established at trial and which Upsher-Smith disputes. The Study — released after the record had closed and after Judge Chappell issued his Initial Decision — was never sponsored or even considered by any fact or expert witness. It was never subjected to scrutiny or analysis at trial. Furthermore, the information underlying the Study has never been made available to Respondents or their counsel. Under the Commission's Rules of Practice and under applicable law, Complaint Counsel's references to the Study should be stricken from this appeal.

I. THE STUDY IS NOT PART OF THE RECORD IN THIS CASE

Rule 3.44(c) of the Commission's Rules of Practice provides: "Immediately upon completion of the evidentiary hearing, the Administrative Law Judge shall issue an order closing

the hearing record." Following almost 40 trial days, more than 8600 pages of transcript and the admission of more than 2500 exhibits, Judge Chappell closed the record in this action on March 28, 2002.

Now, more than seven months later, Complaint Counsel in their Reply Brief cite the Study to introduce new purported facts.[1] Complaint Counsel's invocation of the Study evokes their earlier attempt in their Appeal Brief to introduce new evidence in the form of new price calculations. The Commission rejected that effort, holding that "ascertaining the validity of Complaint Counsel's analysis and the underlying data is a function that would have been more appropriately undertaken within the bounds of the administrative trial." Sept. 27, 2002 Order ("Order") at 3. Here too, the Study was never considered "within the bounds of the administrative trial." The Study is not part of the record. It is not an admitted exhibit. No witness sponsored, defended or otherwise laid any foundation for the Study. Because the Study was not published until July 2002, Respondents have not had an opportunity to (i) review it before its release, (ii) test its source data, (iii) probe its methods, including its sample and its classification of various settlement outcomes, (iv) examine its authors, or (v) present arguments to rebut particular findings. *See* Commission Rule 3.43(d) (providing that when official notice is taken "of a material fact not appearing in evidence of record, opportunity to disprove such noticed fact shall be granted any party making timely motion thereof.").

Complaint Counsel's Reply Brief improperly uses the Study to challenge the testimony of Upsher-Smith expert Dr. William Kerr regarding the likely course and duration of the

[1] In its answering brief, Upsher-Smith did not cite to or allude to the Study. Schering, in its answering brief, mentioned the Study in passing (*see* Schering Answering Br. at 6), although not as a way of introducing new factual evidence upon which it bore the burden of proof.

Schering/Upsher-Smith patent litigation, had it not settled. *See* Reply Br. at 37-38.[2] Well before trial, however, Complaint Counsel were given notice that Dr. Kerr would testify about patent litigation. Complaint Counsel received copies of Dr. Kerr's initial and rebuttal reports. After reviewing the reports, Complaint Counsel were afforded a full opportunity to test Dr. Kerr's opinions through a lengthy pre-trial deposition and through extensive cross-examination at trial. By the time the record closed, however, Complaint Counsel never called any witness to rebut Dr. Kerr's testimony on these matters.

Complaint Counsel also use the Study to dispute the need for the Settlement Agreement to prohibit Upsher-Smith from marketing its Klor-Con M20 product under a different name (the subject of Dr. Kerr's testimony), and the prospects for settlement between Upsher-Smith and Schering without fair-market compensation for the licenses. *See* Reply Br. at 29 n.27, 46. However, the Study cannot supplement or supplant the full trial record, which details every step of the actual negotiations through the trial testimony of negotiation participants (*e.g.*, Ian Troup, John Hoffman and Nicholas Cannella). Moreover, use of the Study to document the "actual experience" of branded and generic firms in other cases beyond those subject to testimony at trial (Reply Br. at 46) is inappropriate because (i) Upsher-Smith has not been provided with the opportunity to disprove the disputed facts in the Study (*see* Commission Rule 3.43(d)), and (ii) no factual showing has been made that such new cases are similar to the factual scenario facing Upsher-Smith and Schering.

The Sixth Circuit's ruling in *United States v. Bonds*, 12 F.3d 540 (6th Cir. 1993), is instructive. In that case, the district court refused to suppress incriminating DNA evidence. *Id.* at 551. After the defendant's conviction, the National Research Committee ("NRC") of the

[2] Complaint Counsel even challenge their own expert, Professor Martin Adelman. *See* Reply Br. at 38.

National Academy of Sciences issued a study critical of the type of DNA evidence admitted against the defendant. *Id.* at 552. According to the Sixth Circuit: "The report was authored by a committee of scientists, legal academicians, ethicists, and a federal judge, including Dr. Eric Lander, the court's witness in the *Frye* hearing." *Id.* The study was also subject to peer review. *Id.* Notwithstanding the study's impressive authorship and subjection to peer review, the Sixth Circuit granted the Government's motion to strike the defendant's reference to the study from the defendant's appellate brief, holding: "the NRC report was not available to the magistrate judge or the district judge when they ruled on the motion to suppress. We cannot consider a report that is not part of the record." *Id.* at 552.

Other circuit courts similarly have found that reliance on facts not in the record is inappropriate. *See, e.g., United States v. Bosby*, 675 F.2d 1174, 1181 n.9 (11th Cir. 1982) (holding that appellate court could not consider affidavits not before the trial court); *Sovereign News Co. v. United States*, 690 F.2d 569, 571 (6th Cir.1982) ("A party may not by-pass the fact-finding process of the lower court and introduce new facts in its brief on appeal."); *United States v. Allen*, 522 F.2d 1229, 1235 (6th Cir. 1975) (holding that an appellate court cannot consider material in a brief that is not part of the record).

Because Judge Chappell never had a chance to consider the Study, Complaint Counsel's reference to the Study should be stricken. To hold otherwise — particularly in light of Complaint Counsel's full opportunity to test Dr. Kerr and rebut his opinion at trial — would violate Rule 3.44(c),[3] and undermine the notion that "ascertaining the validity" of new facts is "more appropriately undertaken within the bounds of the administrative trial." Order at 3.

[3] Other federal agencies similarly exclude non-record evidence. *See, e.g., Mademoiselle Knitwear, Inc.*, 297 N.L.R.B. 272, n.1 (1989) (striking material sought to be introduced after the close of the record); *Baker Mine Services, Inc.*, 279 N.L.R.B. 609, 611 n.1 (1986) (striking materials sought to be introduced after the close of the record because "consideration of these documents would deny the parties the

II. THE STUDY IS NOT SUITABLE FOR JUDICIAL OR OFFICIAL NOTICE

Not only does the Study fall outside the record, but it also falls outside the range of facts for which judicial notice is appropriate. Rule 201(b) of the Federal Rules of Evidence permits courts to take judicial notice of matters under limited circumstances, making clear that a judicially noticed fact "must be one not subject to reasonable dispute." To be suitable for judicial notice, the fact must be "generally known" or "capable of . . . ready determination." Fed. R. Evid. 201(b).

The Advisory Committee's notes to Rule 201 state: "The usual method of establishing adjudicative facts is through the introduction of evidence, ordinarily consisting of the testimony of witnesses. If particular facts are outside the area of reasonable controversy, this process is dispensed with as unnecessary. A high degree of ***indisputability*** is the essential prerequisite." Fed. R. Evid. 201 advisory committee's note (emphasis added); *Hennessy v. Penril Datacomm Networks, Inc.*, 69 F.3d 1344, 1354 (7th Cir. 1995) (same); *see also Lussier v. Runyon*, 50 F.3d 1103, 1114 (1st Cir. 1995) ("Courts have tended to apply Rule 201(b) stringently — and well they might, for accepting disputed evidence not tested in the crucible of trial is a sharp departure from standard practice").

In this case, Complaint Counsel cite the Study ***not*** because its findings are indisputable, but precisely to dispute Dr. Kerr's trial testimony. Because Complaint Counsel rely on the Study to dispute Dr. Kerr's testimony, the purported facts Complaint Counsel now advance for the first

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opportunity for voir dire and cross-examination and would violate the Board's Rules and Responsibilities."); *Admin. v. Jesse Frank Putnam*, 1976 WL 19054, *4 (N.T.S.B.) (declining to consider new evidence because the record was closed "and respondent was given sufficient opportunity to present all his evidence at the hearing."); *Bibby v. Dep't of Transp.*, 33 M.S.P.R. 88, 89-90 (1987) (excluding report furnished after the record had closed); *Avisano v. U.S. Postal Serv.*, 3 M.S.P.B. 308, 310 (1980) (same).

time in their Reply Brief necessarily lack the "high degree of indisputability" that is a "prerequisite" to judicial notice.

Nor can the facts about the elements of various patent infringement settlements and litigation outcomes be characterized as "generally known" or "capable of accurate and ready determination." Fed. R. Evid. 201(b). The Study is the result of a series of nonpublic subpoenas outside the *Schering* litigation. The Commission staff spent more than a year developing the Study, and the Study adopts a complex classification system for various Paragraph IV litigation settlements.

In circumstances similar to those present here, one FTC judge has held that official notice is improper. *See In the Matter of Litton Industries, Inc.*, 97 F.T.C. 1, 54-55 (1981) (rejecting respondent's request to take official notice of a study obtained ***after the close of the record***, noting "that several experts, all with impressive qualifications, have testified to such opposite effect on this very topic in this case," and thus, "it can hardly be stated that still another study 'cannot reasonably be questioned' as to accuracy. This simply is not the type of evidence of which I can take official notice."). This is consistent with federal court rulings. *See, e.g.*, *Lussier*, 50 F.3d at 1114 (admonishing the district court not to take judicial notice after the close of the evidence: "judges may not defenestrate established evidentiary processes, thereby rendering inoperative the standard mechanisms of proof and scrutiny"); *United States v. Bines*, Nos. 94-50082, 94-50212, 94-50382, 1995 WL 490152, *7 n.3 (9th Cir. Aug. 15, 1995) (declining to take judicial notice of "two recent studies concerning race-based prosecutions in the Central District of California," because the studies contained disputed facts); *Bonds*, 12 F.3d at 553 (declining to take judicial notice of NRC study because "if we were to take judicial notice of this article, the Government would be precluded from rebutting the report with expert testimony,

as both sides were permitted to do for the reports and articles submitted to the magistrate judge"); *Cooperativa de Ahorro y Credito Aguada v. Kidder, Peabody & Co.*, 993 F.2d 269, 272-273 (1st Cir. 1993) (holding that the district court improperly took judicial notice of financial periodicals that were not offered in evidence); Commission Rule 3.43(d) (precluding ALJ or Commission from taking official notice of a material fact unless parties have an opportunity to disprove it).

Nor do courts take judicial notice of the contents of government studies as a substitute for evidence. *Carley v. Wheeled Coach*, 991 F.2d 1117, 1126 (3d Cir. 1993) (rejecting decision to take judicial notice of a government vehicle study because "[t]he government may perform various tests on vehicles, but the quantity and nature of those tests are not matters of common knowledge, nor are they readily provable through a source whose accuracy cannot reasonably be questioned); *U.S. v. Wagner*, No. 98-50707, 2001 WL 1104591, *1 n.1 (9th Cir. Sept. 10, 2001) (declining to take judicial notice of inferences from an FDIC manual because "they include disputed facts"); *Korematsu v. United States*, 584 F. Supp. 1406, 1415-16 (N.D. Calif. 1984) (declining unopposed request for judicial notice of a government report because judicial notice is not "a substitute for more rigorous requirements and careful factfinding.").

Not only do Complaint Counsel seek to use the Study to support a disputed point, but they misstate the Study's findings. Complaint Counsel seek to downplay the chilling effects of the novel "rule of law" they urge by asserting that the settlements they oppose have already ended: "while publicity has put an end to settlements with payments, settlements of Paragraph IV cases have continued." Reply Br. at 46 (citing Study at vii-viii, 27). But the discussion cited by Complaint Counsel (*see* Study at vii-viii) is limited to ***Interim Agreements***, such as those in *Hoechst/Andrx* or *Abbott/Geneva* rather than Final Settlements such as the one here. The Study

states: "Between April 1999 (shortly after FTC investigations in this area became public) and the end of the period covered by this study, brand-name companies and first generic applicants have not entered agreements similar to the ***Interim Agreements*** challenged by the FTC." Study at vii-viii (emphasis added). The July 2002 FTC Study expressly distinguishes Interim Agreements, such as the *Hytrin* case, from Final Settlements. Chapter Three of the Study devotes separate sections to "Final Settlements," (*see* Study at 31-34), and "Interim Agreements," (*see id.* at 34-35). *See also id.* ("In addition to the 20 final settlements, 4 interim settlements with the first generic were produced."); *id.* at 34 (Interim Agreements section). The Study expressly classifies the Schering agreement at issue in this proceeding as a "Final Settlement" — because it ended the Klor-Con M20 patent litigation — not as an Interim Agreement. Study at 29 n.10 ("For a discussion of these agreements, see *Schering-Plough Corp.*, *supra* n.2.").[4]

Finally, any consideration of the Study is particularly unfair because it was prepared *ex parte* by, among others, members of Complaint Counsel's staff who participated in the trial. Indeed, the Study includes the June 1997 Agreement between Upsher-Smith and Schering. *See* Study at 30. Because the Study was created during the litigation with the assistance of Complaint Counsel advocates, its use in this case is improper. *See United States v. Gadson*, 829 F. Supp. 435, 438 (D.D.C. 1993) (declining government's request to take judicial notice of facts contained in probation officer's report: "The Court is particularly opposed to doing so because it

[4] Another reason why official notice of various selective portions of the Study — raised for the first time in a Reply Brief — should be disallowed is that Complaint Counsel's citation is highly selective and untested. Without being tested by witnesses subject to cross-examination, aspects of the Study that support Respondents are not brought out at all. *See, e.g.*, Study at 16 (nearly half of all Paragraph IV litigation settlements involve a "brand payment"); Study at viii (pendency of patent infringement suit prevents generic entry).

knows that the information contained in the [report] is often given to the Probation Department by the Government prosecutors").

CONCLUSION

For the foregoing reason, the Commission should strike Complaint Counsel's reliance on the Study and disregard the Study from further consideration in this case.

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Respectfully submitted,

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