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

COMPLAINT COUNSEL'S OPPOSITION TO UPSHER'S MOTION TO STRIKE RELIANCE ON THE COMMISSION'S *GENERIC DRUG STUDY*

The Commission recently issued a groundbreaking empirical study -- *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002) -- that examines settlements of patent litigation from 1993-2001 between branded and generic drug companies under the Hatch-Waxman Amendments. Undertaken at the request of Congress, the study found that in some cases pharmaceutical companies have settled such litigation through arrangements that do not involve a payment from the branded firm to the generic entrant to forebear entry, and that these types of arrangements have been increasingly used in recent years. In our reply brief, we pointed out that these findings from the study contradict claims that so-called "reverse payments" are necessary to settle patent litigation in the Hatch-Waxman context.

Upsher, by moving to "strike reliance" on the *Generic Drug Study*, seeks to preclude the Commission from considering its own study in rendering a decision in this case. But Upsher's motion is off the mark, because while the study is not record evidence to be used to establish the facts needed to prove a violation of law, it can and should be used to inform the legal and policy considerations of the Commission's decision. Such use of extra-record information is well-established, and it is particularly appropriate in the circumstances here. Accordingly, we respectfully request that the Commission deny Upsher's motion to strike.

1. Courts and Administrative Agencies Often Consider Information Outside the Adjudicative Record In Their Decision Making

When confronted with questions of law or policy upon which facts are needed to guide their judgment, courts and administrative agencies have long looked outside the adjudicative record for information that may assist the tribunal in its decision-making process.[1] In doing so, courts have drawn an important distinction between "adjudicative" facts, which are those developed in a particular case for purposes of determining whether a violation of law has occurred, and "legislative" facts, which are those that do not change from case to case but help resolve disputed issues of law and policy. As a leading administrative law treatise elaborates:

> Adjudicative facts usually answer the question of who did what, where, when, how, why, with what motive or intent; adjudicative facts are roughly the kinds of facts that go to a jury in a jury case. Rules of evidence do not limit the kinds of materials a court or agency can use to resolve disputed issues of legislative fact. Legislative facts do not usually concern the immediate parties but are general facts that help the tribunal decide questions of law and policy and discretion.[2]

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[1] *See generally* Richard J. Pierce, Jr., *Administrative Law Treatise* § 10.5, 732-41 (4th ed. 2002).

[2] *Id.* at 732.

This administrative law treatise observes that "authority for the distinction between legislative and adjudicative facts is overwhelming," and discusses how the Supreme Court, the courts of appeal, district courts, and administrative agencies have long used the practice of looking outside the adjudicative record for information that may help resolve issues of law and policy.[3]

In contrast, the cases Upsher cites in its motion to strike largely involve the application of Federal Rule of Evidence 201, which by its very terms concerns only judicial notice of adjudicative facts.[4] Other cases Upsher cites are irrelevant because they involve the exclusion of material whose nature and purpose is unspecified,[5] or address special standards for appeals based

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[3] *Id. See also* Ellie Margolis, *Beyond Brandeis: Exploring the Uses of Non-Legal Materials in Appellate Briefs*, 34 U.S.F.L. Rev. 197, 205 (2000) ("[T]here is no procedural bar to introducing non-legal material in support of appellate arguments, even when it has not been introduced in the trial court proceedings.").

[4] *E.g., United States v. Bonds*, 12 F.3d 540, 553 (6th Cir 1992) (rejecting defendants' request that court take judicial notice of report under FRE 201); *Lussier v. Runyon*, 50 F.3d 1103, 1113-15 (1st Cir. 1995) (reversing district court's reduction of damage award based on extra-record evidence of disputed adjudicative facts); *Cooperative de Ahorro y Credito Aguada v. Kidder, Peabody & Co.*, 993 F.2d 269, 273 (1st Cir. 1993) ("[T]he district court's use of scattered press reports to take judicial notice of an adjudicative fact was beyond the proper scope of judicial notice."); *Korematsu v. United States*, 584 F.Supp. 1406, 1415 (N.D. Cal. 1984); and cases cited at pages 5-7 of Upsher's motion.

[5] *United States v. Bosby*, 675 F.2d 1174, 1181 n.9 (11th Cir. 1982) (declining to consider "an affidavit attached to the [government appeal] brief"); *United States v. Allen*, 522 F.2d 1229, 1235 (6th Cir. 1975) (refusing to consider "two volumes of material not contained in the record"); and cases cited in footnote 4 of Upsher's motion.

on new evidence.[6] In sum, Upsher's motion is based on a misplaced reliance on legal rules that apply to proof of adjudicative facts.[7]

2. Complaint Counsel Seek to Use the *Generic Drug Study* Only to Support the Resolution of Questions of Law and Policy

At page 46 of our reply brief we address policy arguments of two *amici* who filed briefs in support of respondents – the Generic Pharmaceutical Association (GPA) and the Washington Legal Foundation (WLF) – to the effect that a ruling in favor of complaint counsel will raise barriers to generics' exit from patent litigation (GPA at 10), and that generics will be "unable to settle costly and time-consuming patent litigation" (WLF at 20). Consistent with the requirements for briefs of *amicus curiae*, the GPA and WLF raise policy matters that they believe may have ramifications going beyond the rights of the respondents in this case. In response to these policy arguments, our reply referred not only to the record evidence that reverse payments are not necessary to settle patent litigation (*see* CPF 1413-25), but also to the *Generic Drug Study* findings concerning patent settlements in Hatch-Waxman cases.

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[6] *Bibby v. Dep't of Transp.*, 33 M.S.P.R. 88, 1987 MSPB LEXIS 1075 (1987) (applying Merit Systems Protection Board rule governing petitions for review based on new evidence); *Avasino v. U.S. Postal Serv.*, 3 M.S.P.B. 308, 1980 MSPB LEXIS 283 (1980) (same).

[7] Although the Commission often looks to the Federal Rules of Evidence for guidance, the Supreme Court has noted that:

> [A]dministrative agencies like the Federal Trade Commission have never been restricted by the rigid rules of evidence. And of course rules which bar certain types of evidence in criminal or quasi-criminal cases are not controlling in proceedings like this, where the effect of the Commission's order is not to punish or to fasten liability on respondents for past conduct but to ban specific practices for the future in accordance with the general mandate of Congress.

FTC v. Cement Inst., 333 U.S. 683, 705-06 (1947) (citation omitted).

As we noted, the study data show that Paragraph IV cases can be and have been settled without reverse payments. Those settlements typically involved agreements in which the brand company either granted the generic a license to use the brand's patents in exchange for royalties or agreed to supply the generic with the branded product.[8] The study also found that final settlements of Paragraph IV cases have continued since the Commission's enforcement actions involving pharmaceutical settlements began in 1999, and also that the majority of the settlements (six of nine) involving licenses or supply agreements occurred in 2000 and 2001.[9] Such use of the *Generic Drug Study* plainly concerns the policy implications of a finding of liability in this case, not facts needed to establish the violation itself.

The two other findings of the *Generic Drug Study* to which we referred in our reply brief concern relatively minor points and also are not offered to prove adjudicative facts. First, we noted that restraints on the generics' marketing of non-infringing products only appeared in conjunction with settlements involving payments from brand companies to generics.[10] As we noted, such restraints are thus not necessary for parties to settle Hatch-Waxman cases generally, a matter that may be of interest to the Commission in assessing the policy implications of a finding

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[8] The study (at pages 27-31) reports that of twenty final settlements: nine involved a reverse payment; seven involved arrangements where the brand company granted the generic a license; two involved supply agreements allowing the generic to market the brand; and two others were counted as "miscellaneous."

[9] As Upsher's motion notes, our reply brief erroneously cites to pages vii-viii of the study. It should have cited to pages 27-31.

[10] *Generic Drug Study* at 30-31, cited at CCRB at 29 n.27.

of liability in this case.[11] Second, we cited the average length of time for district court litigation, appellate litigation, and appellate reversal rates in Hatch-Waxman Paragraph IV cases.[12] Upsher argues that we use this information to rebut certain testimony of one of its economic experts, William Kerr, who testified about the average length of time it took to complete patent infringement damages actions (not litigation arising under Hatch-Waxman) and the probability of reversal and remand on appeal. But the relevant adjudicative facts concerning the parties in this case are not these industry averages (either for patent litigation generally or for Hatch-Waxman patent cases). Rather, the key adjudicative facts are proven by the direct evidence concerning the parties, which shows that prior to their settlement both were preparing for generic entry before September 2001: Upsher took significant actions to prepare for entry in 1998 (CPF 125-28, 132, 136-39), and Schering was preparing as early as 1997 to respond to imminent generic competition by launching its own generic K-Dur 20 through its Warrick subsidiary (CPF 79-82). The *Generic Drug Study* data on Hatch-Waxman litigation averages are thus not offered to prove facts that establish the violation of law here.

3. Reliance on the *Generic Drug Study* Is Particularly Appropriate Under the Present Circumstances

Reliance on the *Generic Drug Study* as a source from which to draw information useful to resolving issues of law and policy is particularly appropriate under the present circumstances. First, as the Supreme Court has recognized:

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[11] Upsher's argument that the collateral restraints were essential for the parties in this case to reach their agreement is beside the point, given the anticompetitive nature of their agreement.

[12] *Generic Drug Study* at 21, 47, cited at CCRB at 38.

> [Congress created the FTC] with the avowed purpose of lodging the administrative functions committed to it in "a body specially competent to deal with them by reason of information, experience, and careful study of the business and economic conditions of the industry affected," and it was organized in such a manner . . . as would "give [its members] an opportunity to acquire expertness in dealing with these special questions concerning industry that comes from experience."[13]

Second, as some commentators have observed: "The FTC's strengths are best employed in cases that challenge conduct in an industry in which the FTC has gained experience by using its full panoply of powers, by publishing studies and by giving guidance in various forms."[14]

Third, the *Generic Drug Study* is an empirical evaluation of the performance of the Hatch-Waxman Act, an Act that has substantially shaped the current legal environment governing the Food and Drug Administration's approval of generic drug products, and which all parties agree forms an important backdrop to understanding the antitrust issues raised in this litigation. It was undertaken at the request of Representative Henry Waxman, an original co-sponsor of the Hatch-Waxman Act,[15] and it arguably is the best source of information that is readily obtainable about generic drug entry prior to patent expiration.

And, fourth, the study has been relied on by the President of the United States as a basis for his initiative to lower prescription drug prices;[16] it is being relied upon by Congress in

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[13] *FTC v. R.F. Keppel & Bro., Inc.*, 291 U.S. 304, 314 (1934), *quoting* Report of the Senate Committee on Interstate Commerce, 63d Cong. 2d Sess., No. 597, pp. 9, 11 (June 13, 1914).

[14] Report of the ABA Section of Antitrust Law Special Committee to Study the Role of the Federal Trade Commission, 58 Antitrust L.J. 53, 63 (1989) (commonly referred to as the "Kirpatrick II Report").

[15] *Generic Drug Study* at p.1.

[16] *See* "President Takes Action to Lower Prescription Drug Prices: Remarks by the (continued...)

fashioning legislative reform of the Hatch-Waxman Amendments;[17] and it is being relied upon by the Food and Drug Administration in formulating its proposed regulatory changes for dealing with patent listing requirements and the application of 30-month stays on approvals of new drug applications.[18]

Thus, Congress created the FTC to develop industry expertise and to use this expertise in evaluating business practices that may violate the law; the FTC has developed such expertise in the area of the Hatch-Waxman Amendments through the process of preparing the *Generic Drug*

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[16](...continued)
President on Prescription Drugs, the Rose Garden," at 1 (October 21, 2002), available at www.whitehouse.gov/news/releases/2002/10/print/20021021-2.htm ("For more than a year, the Federal Trade Commission has investigated delays and abuses in the process of bringing generic drugs to market. I have reviewed the FTC findings and I am taking immediate action to ensure that lower cost, effective generic drugs become available to Americans without any improper delays.")

[17] *See, e.g.*, U.S. Senator Patrick Leahy, "Senate Passes Leahy Bill Targeting Sweetheart Deals that Delay Low-Cost Generic Drugs," at 1 (November 19, 2002), available at http://leahy.senate.gov/press/200211/111902.html ("The Federal Trade Commission recently issued a study and report on the generic drug marketplace, and one of the agency's two recommendations for improving access to generic drugs was simply the passage of [Leahy's] Drug Competition Act [S. 754]."); U.S. Senator John McCain, "Broad Coalition Helps Schumer-McCain Generic Drug Bill Sweep through Senate," at 2 (July 31, 2002), available at http://mccain.senate.gov/genericfinal.htm ("McCain noted that information received by consumers, industry analysts, and the report released yesterday by the Federal Trade Commission as important factors in passing [The Greater Access to Affordable Pharmaceuticals Act, S. 812] by such a wide margin.").

[18] Department of Health and Human Services, Food and Drug Administration, "Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying that a Patent Claiming a Drug Is Invalid or Will Not be Infringed," 67 Fed Reg. 65448 (October 24, 2002) (discussing the FTC's *Generic Drug Study* at length throughout the Federal Register notice and identifying it as one of the bases for the FDA's proposed rule changes).

Study and its law enforcement initiatives in this area;[19] and the President, the Congress, and the Food and Drug Administration all are relying on the FTC's expertise and the *Generic Drug Study's* findings to fashion legislative and regulatory reforms in this vital area. Under these circumstances, 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.[20] Conversely, Upsher is arguing that the Commission must ignore its own expertise and experience -- developed through a well-respected study -- in addressing the legal and policy issues arising in this case.[21]

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The Commission's *Generic Drug Study* is an important contribution to understanding the performance of the Hatch-Waxman Act and the generic drug marketplace. Contrary to Upsher's charge, we have cited the study not to resolve adjudicative facts in dispute in this appeal, but

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[19] *See, e.g., Abbott Laboratories*, Dkt. No. C-3945 (May 22, 2000) (consent order); *Hoechst Marion Roussel, Inc.*, Dkt. No. 9293 (May 8, 2001) (consent order).

[20] Indeed, Chairman Muris, writing as a law professor prior to his appointment as FTC Chairman, has criticized the Commission for failing to make use of similar FTC studies to help resolve issues arising in administrative adjudication before the Commission. *See* Timothy J. Muris, *California Dental Association v. Federal Trade Commission: The Revenge of Footnote 17*, 8 S. Ct. Econ. Rev. 265, 293 (2000) ("The FTC did not, however, discuss the considerable body of empirical evidence, some of which the Commission had itself previously developed, demonstrating that the [Supreme] Court's fears about the impact of professional advertising on consumers are unwarranted.").

[21] At the end of its motion, Upsher casually asserts that "*any consideration*" of the study in this litigation would be "particularly unfair," because it "was created during the [instant] litigation" and some FTC staff members who participated in the trial were also involved in preparation of the study report." Motion at 8 (emphasis added). It is unclear exactly what Upsher means to suggest by this, but any insinuation that the study's findings are somehow infected with bias or were the product of improper *ex parte* communications is entirely unsupported and without merit.

rather we have made appropriate reference to the study where it may assist the Commission's thinking about issues of law and policy raised by respondents and their *amici* concerning the possible consequences of antitrust enforcement in this arena. Accordingly, we respectfully request that the Commission deny Upsher's motion to strike.

Respectfully submitted,

Markus H. Meier
Elizabeth R. Hilder
Karan Singh
Counsel Supporting the Complaint

December 9, 2002

CERTIFICATE OF SERVICE

I, Karan R. Singh, hereby certify that on December 9, 2002:

I caused one original and twelve copies of Complaint Counsel's Opposition to Upsher's Motion to Strike Reliance on the Commission's *Generic Drug Study* to be served by hand delivery, and one copy by electronic mail, upon the following-

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

I caused one copy of Complaint Counsel's Opposition to Upsher's Motion to Strike Reliance on the Commission's *Generic Drug Study* to be served by hand delivery upon the following-

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission - Room 104
600 Pennsylvania Ave, NW
Washington, DC 20580

I caused copies of Complaint Counsel's Opposition to Upsher's Motion to Strike Reliance on the Commission's *Generic Drug Study* to be served by facsimile and regular mail upon the following-

Laura S. Shores, Esq.
Howrey Simon Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2402

Christopher M. Curran, Esq.
White & Case LLP
601 13th Street, N.W.
Washington, D.C. 20005

Karan R. Singh