

UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION

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

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In the Matter of

SCHERING-PLOUGH CORPORATION,  
a corporation,

UPSHER-SMITH LABORATORIES, INC.,  
a corporation,

and

AMERICAN HOME PRODUCTS CORPORATION,  
a corporation.

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DOCKET NO. 9297

ORDER GRANTING MOTION FOR LEAVE TO FILE REPLY MEMORANDUM;  
DENYING MOTION TO STRIKE RELIANCE ON FTC STUDY; AND  
PERMITTING EACH PARTY TO FILE A BRIEF  
ADDRESSING CITED FACTS CONTAINED THEREIN

This matter is before the Commission on Upsher-Smith's Motion to Strike Complaint Counsel's Reliance on the July 2002 FTC Study. Upsher-Smith has also filed a Motion for Leave to File Reply Memorandum in Support of its Motion to Strike. The Commission grants the Motion for Leave and denies the Motion to Strike.

In July, 2002, the Commission released an empirical study examining competitive implications of patent litigation under the Hatch-Waxman Act, entitled *Generic Drug Entry Prior to Patent Expiration: An FTC Study* ("Study"). The Study was undertaken at the behest of Congress, to whom the Study's findings were directed. It has since been relied upon for policymaking by the President of

the United States, Congress, and the Food and Drug Administration.<sup>1</sup>

The Study was first cited in this case by Respondent Schering-Plough in its Answering Brief. Complaint Counsel subsequently included several references to the Study in their Reply Brief.

Respondent Upsher-Smith argues in its motion that Complaint Counsel's reliance on this Study in their Reply Brief should be stricken because the Study is not part of the record in this case, and because Respondents have not had an opportunity to examine its data, methodology, and authors or to present arguments in rebuttal. Upsher-Smith argues further that the Study falls outside the range of facts for which judicial notice is appropriate pursuant to Federal Rule of Evidence 201(b).

After careful consideration, the Commission finds these arguments to be unpersuasive. The Commission Rules of Practice, which govern these proceedings, acknowledge that the Commission may take official notice of "a material fact not appearing in evidence of record."<sup>2</sup> We find that the Study has been cited by both Complaint Counsel and Schering in broad context and in limited scope, and that the general findings for which it is cited may be instructive to the Commission with regard to matters of public policy and discretion. Accordingly, the Commission will take official notice of the Study. Rule 3.43(d) provides further that when

any decision . . . of the Commission rests, in whole or in part, upon the taking of official notice of a material fact not appearing in evidence of record, opportunity to disprove such noticed fact shall be granted any party making timely motion therefor.<sup>3</sup>

The Commission cannot of course now determine whether any decision it reaches in this proceeding will rest, in whole or in part, upon the taking of official notice of a fact contained in the Study which is both material and "not appearing in evidence of record. . . ." Consequently, nothing in this Order should be construed to suggest in any way that the "opportunity to disprove" described in Rule 3.43(d) must be afforded any Party to this proceeding as a matter of right. Nevertheless, as a matter of discretion, the Commission has determined to permit any Party wishing to address the findings for which the Study is cited to file a brief, not to exceed 15 pages, no later than January 27, 2003, and to permit any other Party to file a brief in opposition, not to exceed 15 pages, no later than February 10, 2003.

Accordingly,

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<sup>1</sup>Complaint Counsel's Opposition to Motion to Strike at 7-8.

<sup>2</sup> 16 C.F.R. §3.43(d) (2002).

<sup>3</sup> Id.

IT IS ORDERED that Respondent Upsher-Smith's Motion for Leave to File Reply Memorandum in Support of its Motion to Strike be and it hereby is granted;

IT IS FURTHER ORDERED that Upsher-Smith's Motion to Strike Complaint Counsel's Reliance on the July 2002 FTC Study be and it hereby is denied; and

IT IS FURTHER ORDERED that any Party seeking to disprove cited facts contained in the Study may file a brief, not to exceed 15 pages, no later than January 27, 2003. Any other Party may file a brief in opposition, not to exceed 15 pages, no later than February 10, 2003.

By the Commission.

Donald S. Clark  
Secretary

ISSUED: January 6, 2003