

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION



In the Matter of

SCHERING-PLOUGH CORPORATION,
a corporation,

Docket No. 9297

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

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REDACTED

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Schering's later forecasts projected that generic K-Dur 20 would have an even more substantial impact on branded K-Dur 20.

Troup, initially requested a \$60-70 million payment from Schering, stating that Upsher needed

[REDACTED]

[REDACTED]

it would win the patent litigation, enter the market, and thereby open the floodgates to other

[REDACTED]

unconditional payments to license a product. Even when a product could represent a new therapeutic class, Schering has paid less than \$30 million unconditionally.

1

2

[REDACTED]

[REDACTED]

3

[REDACTED]

1997, a federal district court enjoined the FDA from applying its successful defense regulation

[REDACTED]

Developments after the Upsher settlement, however, made it appear less likely that

Upsher would obtain its 180 day exclusivity. In July 1997, Upsher obtained a decision from the FDA that

[REDACTED]

[REDACTED]

[REDACTED]

77

[REDACTED]

[REDACTED]

[REDACTED]

successful defense regulation valid and binding on the FDA. See *Granutec, Inc. v. Shalala*,
1997 WL 1403894 (E.D.N.C. July 3, 1997); *rev'd*, 1998 U.S. App. LEXIS 6683 (4th Cir. 1998).

In November of that year, the FDA announced that it would adhere to the regulation and grant

[REDACTED]

[REDACTED]

to delay entry, however, AHP wanted a payment from Schering to replace the revenues it would

lose from the delay. AHP's request was denied.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

It was noted that AHP's request for a payment from Schering was denied.

[REDACTED]

[REDACTED]

Finally, AHP agreed not to market more than one version of generic K-Dur 20 between January 2004 and September 2006.

In addition to the direct payment for delayed entry, Schering paid AHP a total of \$15 million ostensibly for two products it licensed from AHP. The parties did no valuation of the products before the settlement, and AHP has admitted that payment under those licenses made

Because these payments were in addition to the direct payment for delayed entry, the settlement

from the agreements, consumers had to pay monopoly prices longer than if the settlements did not have a payment and longer than what was expected had the parties litigated their patent cases.

III. Legal and Factual Matters to Be Decided

The Commission's complaint charges that Schering's agreements with Upsher-Smith and AHP are: (1) unreasonable restraints of trade that delayed expected generic entry; (2) monopolization by Schering of the potassium chloride supplement market and narrower markets

[REDACTED]

[REDACTED]

Minnesota-manufactured products "in every state in the United States"),⁶ at present it remains an

issue to be decided.

Each agreement restrains trade in two ways. Overall, Upsher and AHP each agreed to delay their respective entry in exchange for a share of Schering's monopoly profits. In addition, each agreement prohibits Upsher and AHP respectively from developing or marketing a noninfringing version of K-Dur 20.

1. *Payments to Delay Entry*

Complaint counsel will prove that the respondents entered into agreements not to compete, and that these agreements are *per se* unlawful and also unlawful under the rule of reason. In proving the violations, we will establish that: Schering, Upsher-Smith and AHP are potential competitors; in settling their patent litigation, they entered into agreements not to

- Schering's payments induced Upsher-Smith and AHP to agree to a later entry date than

the agreements had later generic entry dates than the respondents expected had the cases been litigated;

the Nippon SD and other licenses were available to transfer the payment for delay and

respondents predict that generic K-Dur 20 will take almost all of its market share from K-Dur 20 and will price at a significantly lower price, and by the beginning of trial, there will be evidence on generic K-Dur's actual impact on the sales of K-Dur 20, which will confirm the predictions of

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

relevant market.

[REDACTED]

[REDACTED]

[REDACTED]

this failure to produce. As to any minor disputes, Schering has not responded to complaint

when it will complete its discovery. Although complaint counsel requested a 3.33(c) deposition on Schering's financial condition on August 9, 2001, Schering, until recently, had not made a witness available or provided any dates for the deposition. Schering, however, did not object to

counsel's ability to prepare for depositions and our expert's ability to prepare their initial, and now, rebuttal reports. We sent AHP a letter on September 13, requesting a date by which AHP will complete its production. AHP now states that it will "substantially comply" by September 27, 2001. Because AHP will not commit to a date that it will complete its production, complaint counsel, on September 17th, moved to compel AHP to complete its production by October 3, 2001.

D. Expert Discovery

schedule, complaint counsel has less than two weeks to submit rebuttal reports in response to the respondents' 23 expert witnesses and 27 business days to depose all of the respondents' experts.

Because the respondents have not yet noticed complaint counsel's experts, complaint counsel

CERTIFICATE OF SERVICE

paper copies, and an electronic copy of Complaint Counsel's Statement of the Case to be filed with the Secretary of the Federal Trade Commission, and that two paper copies were served by hand upon:

Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission, Room 104
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

and the original copy of the Complaint Counsel's Statement of the Case to be filed with the Secretary of the Federal Trade Commission.