UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

In the Matter of	)	
	)	
Schering-Plough Corporation,	)	
a corporation,	)	
	)	
Upsher-Smith Laboratories,	)	Docket No. 9297
a corporation,	)	
	)	
and	)	
	)	
American Home Products Corporation,	)	
A corporation.	)	

RESPONDENT SCHERING-PLOUGH CORPORATION'S RESPONSE TO COMPLAINT COUNSEL'S MOTION TO FOR LEAVE TO FILE AN APPEAL BRIEF EXCEEDING THE WORD LIMIT IN THE COMMISSION'S RULES OF PRACTICE

Respondent Schering-Plough Corporation ("Schering") respectfully submits this memorandum in response to Complaint Counsel's motion to submit an oversized brief on appeal ("the Motion").

Complaint Counsel's motion correctly states that Schering consented to the relief sought in the motion, provided that Schering is also granted leave to submit a brief which exceeds the word limit. Schering did not consent, however, to Complaint Counsel's use of the Motion as a vehicle for presenting a highly misleading preliminary brief on the merits of the appeal. We take a particularly dim view of Complaint Counsel's graceless and disrespectful attempt to blame the Commission's Administrative Law Judge for a loss that in fact resulted from Complaint Counsel's own failure to prove their case.

Complaint Counsel first complain that Judge Chappell incorrectly used a "substantial evidence" standard in evaluating the evidence – a standard which Complaint Counsel claim is unduly generous to the party bearing the burden of proof. This is an odd position for Complaint Counsel to take, since Complaint Counsel bore the overall burden. But in any event, "substantial evidence" is the standard which the United States Congress requires Administrative Law Judges to apply when making findings of fact. *See* 5 U.S.C. § 556(d).[1] And in the context of fact finding by ALJs, the Supreme Court of the United States has construed "substantial evidence" to have the same meaning as "preponderance of evidence," the standard that Complaint Counsel argues should govern the case. *Steadman v. SEC,* 450 U.S. 91, 98-101 (1981) (substantial evidence requirement in § 556(d) of the APA means "preponderance" of the evidence); *Freeman v. Office of Workers Comp.,* 988 F.2d 706, 711 (7th Cir. 1993) (stating that the APA's "reliable, probative and substantial evidence" language "establishes a preponderance-of-the-evidence standard of proof"); *Director v. Greenwich Collieries, et al.,* 512 U.S. 267, 290 (1994) (Souter, dissenting) (same).[2]

Proof by a "preponderance" means proof that "the existence of fact is *more probable* than its nonexistence"[3]; and a review of Judge Chappell's initial decision shows clearly that he used the statutory "substantial evidence" standard correctly, to mean the same as "preponderance" of the evidence. Indeed, with all due respect to Complaint

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1 "Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof . . . . A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence." 5 U.S.C. § 556(d).

2 In fact, when the Commission deleted the language "substantial evidence" from its rule, it expressly noted that "the term '*substantial evidence*' … is meant to refer to … the quantum of evidence (in most cases *a preponderance*) needed to support findings of fact." FTC Rules of Practice, 66 Fed. Reg. 17,622, 17,626 (2001) (codified at 16 C.F.R. § 3.51(c)) (emphasis added). The deletion was not meant to change the preponderance standard of proof. *Id.*

3 *Concrete Pipe and Products of California, Inc. v. Construction Laborers Pension Trust,* 508 U.S. 602, 622 (1993).

Counsel, it is ludicrous to suggest that Judge Chappell made findings of fact whose existence he found *less* probable than their nonexistence. And his findings favorable to respondents show clearly that he concluded in each case that respondents' proof was stronger than Complaint Counsel's.

Thus, most of the trial was devoted to Complaint Counsel's efforts to prove that the $60 million Schering paid Upsher-Smith for rights to Niacor-SR was not a bona fide payment for fair value, and that the $60 million was instead a sham payment for delay. Judge Chappell noted in his Initial Decision that this issue was dispositive: "Complaint Counsel acknowledged that its case would fail if it could not prove that Schering paid Upsher-Smith for delay." I.D. at 106. Judge Chappell continued "the *fact* testimony was unrebutted and credible in establishing that the [Niacor-SR] licensing agreement was a bona fide arms length transaction." *Id.* at 107. Judge Chappell went on to state that "to prove that the $60 million payment from Schering to Upsher-Smith was not a bona fide royalty payment . . . . Complaint Counsel proffered Nelson L. Levy, 'an expert in the field of pharmaceutical licensing and pharmaceutical evaluation.'" *Id*. at 109. Then, for reasons described in great detail and with great precision over sixty pages of the Initial Decision, Judge Chappell concluded that "Dr. Levy's testimony is contradicted by the *greater weight of the evidence*." *Id.* at 109. In other words, Judge Chappell found that the preponderance of the evidence, and more, supported respondents' position.

Moreover, Complaint Counsel's objection to the standard of proof is simply perplexing. Complaint Counsel argue that the statutory "substantial evidence" standard referred to by Judge Chappell is *more lenient* than the preponderance of the evidence standard. As set forth above, the standards are the same. But even if Complaint Counsel were correct that "substantial evidence" is more generous, it would be peculiar for them to complain about it, since Complaint Counsel bear the overall burden. As Judge Chappell noted with respect to the ESI settlement:

> As discussed *supra*, Complaint Counsel has the burden of proof on all violations alleged in the Complaint. Respondent Schering had no duty or requirement to offer any evidence on the ESI agreement should Complaint Counsel not do so. Complaint Counsel did not present sufficient substantial, reliable evidence to support a conclusion that ESI could have or would have entered the market before the date set on the settlement agreement. Complaint Counsel also did not present sufficient substantial, reliable evidence to support a conclusion that the Schering-ESI patent litigation would have settled without the provision for the licensing agreement for enalapril and buspirone being part of that settlement or that any payment was not for fair value. Accordingly, there is no substantial, reliable evidence to conclude that the $15 million was paid only for unlawful delay.

I.D. at 112. Thus, to the extent that an overly generous standard was applied, it only benefited Complaint Counsel. And if Complaint Counsel were correct, it would mean that Judge Chappell found that Complaint Counsel failed even to satisfy a lesser burden of proof.

Complaint Counsel also attack Judge Chappell for finding that the numerous other potassium chloride substitutes on the market were "therapeutically equivalent" to K-Dur 20. Complaint Counsel imply, incorrectly, that Judge Chappell relied for this finding only on Dr. Addanki, Schering's economist, who is not a medical expert. *See* Motion at p. 6. In fact, however, Judge Chappell relied on *Complaint Counsel's own witnesses,* who testified without equivocation that these other products were "therapeutically equivalent" to K-Dur 20. *See* I.D. at 88-89 & IDF ¶¶ 49-55.[4] Complaint Counsel's *own witnesses* demolished Complaint Counsel's theory of the market; and the Administrative Law Judge quite properly relied on their testimony.

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4 This testimony came out on questioning by Respondents and by the Judge. Tr. 1:144, 174-75 (Goldberg). We do not know whether Complaint Counsel deliberately called witnesses who would undermine their theory of the market, or whether they never bothered to interview the witnesses before calling them.

Complaint Counsel make other baseless attempts to blame the Commission's Judge for their failures. They blame him, for example, for even-handedly enforcing procedural rules regarding rebuttal testimony against them, *see* Motion at pp.9-10; and they incorrectly argue that one of his findings of fact contradicted another finding of fact. *See* Motion at pp. 7-8. We will respond to these claims in our brief on appeal if Complaint Counsel present them in the appropriate way in their brief.

The point for now is simply that Complaint Counsel's problems are not the result of mistakes by the Administrative Law Judge, who wrote an exceedingly thorough and careful Initial Decision. Complaint Counsel's problems flow from their own failure of proof. Complaint Counsel called only three fact witnesses. These fact witnesses knew nothing of the facts in this case and testified only about the potassium chloride market. And two of these witnesses *undermined* Complaint Counsel's theory of the market by stating that the numerous competing potassium chloride products were therapeutically equivalent to K-Dur 20. Complaint Counsel's proof on the merits of the Complaint consisted of two experts – an economist and a so-called licensing expert. The Administrative Law Judge found their testimony to lack credibility for reasons carefully and thoroughly stated in his decision.

Respondents, by contrast, called numerous fact witnesses who were knowledgeable about the settlement discussions, and others who were knowledgeable about the Niacor-SR license transaction. Judge Chappell found their testimony to be "credible"; and he found their testimony powerfully supported by *contemporaneous documents* to which he made repeated reference in his opinion. I.D. at 107, 110-11.

That is why Complaint Counsel lost this case.

CONCLUSION

Schering has no objection to Complaint Counsel's desire for an expansion of the word limit applicable to their brief. We do, however, request an equivalent expansion for

our brief. As evidenced by the mischaracterizations of the record contained in Complaint Counsel's motion, additional space will undoubtedly be necessary to respond to inaccurate depictions of the record.

Respectfully submitted,

John W. Nields, Jr.
Marc G. Schildkraut
Laura S. Shores
Charles A. Loughlin
HOWREY SIMON ARNOLD & WHITE, LLP
1299 Pennsylvania Ave., N.W.
Washington, D.C. 20004
(202) 783-0800

Attorneys for Respondent
Schering-Plough Corporation

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