UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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 **PUBLIC VERSION**

COMPLAINT COUNSEL'S OPPOSITION TO UPSHER-SMITH'S MOTION TO EXCLUDE REBUTTAL WITNESSES

Upsher-Smith's motion is the latest salvo in respondents' strategy to deprive this Court and the Commission of relevant and reliable evidence that bears directly on the anticompetitive nature of the challenged agreements. Before this hearing even began, respondents set this strategy in motion by filing countless papers seeking to exclude damaging evidence sought to be introduced by complaint counsel during our case-in-chief, including:

- sworn party admissions found in the transcripts of Schering and Upsher employees demonstrating, among other facts, that during the settlement negotiations, Upsher repeatedly sought compensation from Schering in return for Upsher's commitment to keep its generic version of K-Dur 20 off the market;

- contemporaneous business documents from respondents' own files demonstrating, among other facts, that Schering knew a pre-requisite to any settlement was providing Upsher a guaranteed income stream to make up for the income they had projected to earn from the sales of Upsher's generic K-Dur 20 product; and

- testimony of two expert witnesses, which shows, among other facts, that the $60 million non-contingent payment could not have been for the Niacor-SR license – the parties' only asserted

justification for the extraordinary payment – and, accordingly, that the agreement is anticompetitive and harms consumers.

After failing to exclude most of our case-in-chief, Upsher now seeks to exclude virtually all of our rebuttal witnesses, so as to let the self-serving testimony of Upsher (and Schering) employees go unrebutted. This motion should be denied in its entirety, because the evidence at issue constitutes fair rebuttal and is necessary to provide this Court and the Commission – the "tribunal encharged with ultimate responsibility for conducting the proceeding and determining its merits" – with a full and complete record upon which it may discharge such responsibility.[1]

LEGAL STANDARD

Complaint counsel "are entitled to rebut evidence adduced on behalf of respondents" in Commission proceedings and it is commonly done.[2] Rebuttal is "time given to a party to present contradictory evidence or arguments."[3] The purpose of rebuttal evidence is to "explain or rebut evidence" and to respond to "new theories" offered by the opponent.[4] Our rebuttal case will not stray from this purpose. It will not rehash the straightforward anticompetitive theory presented during our

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[1] *In re Foster-Milburn Co. and Street & Finney, Inc.*, 51 F.T.C. 369, 371 (1954).

[2] *In re Modern Methods, Inc.*, 60 F.T.C. 309, 331 (1962); *see, e.g., In re International Telephone & Telegraph Corp.*, 104 F.T.C. 280, 289 (1984) (eleven and one-half days of rebuttal).

[3] *Black's Law Dictionary* 1274 (Bryan A. Garner ed., West Group 7th ed. 1999). Black's further defines "rebuttal evidence" as that which is "offered to disprove or contradict the evidence presented by an opposing party." *Id*. at 579.

[4] *United States v. Tejada*, 956 F.2d 1256, 1266 (2d Cir. 1992); 1 Michael H. Graham, *Handbook of Federal Evidence* §611.13 at 851 (4th ed. 1996); *see also* Charles Alan Wright & Victor James Gold, *Federal Practice and Procedure* §6164 at 381 (1993) (explaining that the purpose of rebuttal evidence is "to explain, repel, counteract, or disprove the evidence of the adverse party").

case-in-chief; rather, it will be a focused response to new defenses raised, theories advanced, and facts introduced during respondents' 19-day defense in which they submitted hundreds of exhibits and called 27 fact and expert witnesses whose testimony covered nearly 5,000 pages of transcript. Upsher's suggestion that we improperly withheld testimony because the number of witnesses expected to be called in our rebuttal case exceeds those in the case-in-chief is without merit. Motion at 2. The scope of rebuttal is properly measured against the scope of respondents' defense, not the case-in-chief. Given respondents' month-long defense, the fact we are calling ten rebuttal witnesses should not be at all surprising.

Rebuttal testimony is not foreclosed, as Upsher claims, simply because it is somehow related to a topic that was addressed during the case-in-chief.[5] The purpose of the case-in-chief is to make a prima facie showing that the challenged conduct is anticompetitive.[6] There is no obligation, nor is it feasible, "to anticipate and negate in [the] case in chief any facts or theories that may be raised on defense."[7] To accept Upsher's rebuttal evidence limitations would compel complaint counsel to anticipate every possible argument respondents might raise before they are raised; to predict every possible factual issue respondents might advance before they are advanced; and then to "present

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[5] The cases Upsher cites do not support its exclusion argument. For example, in *Heatherly v. Zimmerman*, 1993 WL 523995 (D.C. Cir. 1993) (an unpublished decision which cannot even be cited in the D.C. Circuit as precedent pursuant to Rule 28(c)), the district court precluded the plaintiff from calling a rebuttal expert witness because the testimony did not respond to any new facts or theories introduced by defendant, but only reinforced evidence already advanced in her case-in-chief. Here, each rebuttal witness will directly refute new facts or theories presented during respondents' defense.

[6] *See* Complaint Counsel's Opposition to Upsher-Smith's Motion to Dismiss (Feb. 25, 2002).

[7] *Rodriguez v. Olin Corp.*, 780 F.2d 491, 496 (5th Cir. 1986).

evidence in advance to rebut every possible scenario that defendants might paint."[8] This approach "not only would be inefficient but would obfuscate the issues,"[9] and already has been rejected in Commission proceedings:

> The Federal Trade Commission Act and the Commission's practices and procedures do not require Commission counsel to anticipate through clairvoyance respondents' evidence, and incorporate rebutting evidence in the Commission's case in chief.[10]

Indeed, the Commission, in endorsing the ALJ's decision to allow rebuttal testimony in *Modern Methods, Inc.*, cautioned that evidentiary rulings concerning rebuttal testimony "should not be unduly restrictive."

> Questions relating to the precise limits of rebuttal testimony are matters resting largely within the discretion of the Commission, which has ultimate responsibility for conducting the proceeding and determining its merits, and the [ALJ's] rulings in this area should not be unduly restrictive.[11]

In this case, anticipating respondents' evidence and addressing it in our case-in-chief would have been particularly inefficient, because it would have involved rebutting in advance the testimony of more than 30 witnesses listed on respondents' witness lists who never showed up at trial.

The Second Circuit's analysis in *Tejada* also is instructive. There, a defense investigator testified that a police officer could not have seen the defendant carrying a package from his surveillance position. This testimony responded to contrary evidence presented by the police officer during the

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[8] *Tejada*, 956 F.2d at 1267.

[9] *Id.*

[10] *In re Modern Methods, Inc.*, 60 F.T.C. 309, 331 (1962) (initial decision).

[11] *Modern Methods*, 60 F.T.C. at 339 (Commission decision); *see also Foster-Milburn Co.*, 51 F.T.C. at 371-72 (1954) (reversing ALJ's exclusion of rebuttal evidence).

government's case-in-chief. Even though this issue – the ability of the police to observe the defendant – plainly had been raised already by the government, the district court nonetheless allowed a second police officer to testify in rebuttal on the same issue.[12]

As the Fifth Circuit explained in a similar ruling which permitted rebuttal evidence on an issue previously addressed in the case-in-chief: "Logic and fairness lead us to conclude that new evidence for purposes of rebuttal does not mean 'brand new.' Rather, evidence is new if, under all the facts and circumstances, the court concludes that the evidence was not fairly and adequately presented to the trier of fact before the defendant's case in chief."[13]

It makes no difference whether some of our rebuttal evidence could have been presented during the case-in-chief; that is not a reason for its exclusion. Motion at 7. The Commission's decision in *Foster-Milburn* is directly on point. In that case, the administrative law judge excluded rebuttal evidence because it "could and should properly have been presented during the case-in-chief."[14] Concluding that "all the facts. . . would be of aid to an informed determination as to the merits," the Commission, on interlocutory appeal, reversed the ALJ's "unduly restrictive" evidentiary ruling.[15]

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[12] *Tejada*, 956 F.2d at 1266-67.

[13] *Rodriguez*, 780 F.2d at 496.

[14] *Foster-Milburn*, 51 F.T.C. at 371.

[15] *Foster-Milburn*, 51 F.T.C. at 371-72; *see also Tejada*, 956 F.2d at 1266-67; *Benedict v. United States*, 822 F.2d 1426, 1428-1430 (6th Cir. 1987) (reversing as abuse of discretion trial court's exclusion of rebuttal testimony because "it logically belonged in the case-in-chief"); *Martin v. Weaver*, 666 F.2d 1013, 1019-1022 (6th Cir. 1981); *United States v. Luschen*, 614 F.2d 1164, 1170 (8th Cir. 1980) ("[t]he fact that testimony would have been more proper for the case-in-chief does not preclude the testimony if its proper in the case-in-chief and in the rebuttal"); *National Surety Corp. v. Heinbokel*, 154 F.2d 266, 268 (3d Cir. 1946) ("the fact that [evidence] might have been

THE REBUTTAL WITNESSES

1. Max Bazerman: Professor Max Bazerman of the Harvard Business School is one of the nation's preeminent experts in the area of negotiations and settlements. Complaint counsel first identified him as a rebuttal witness on November 15, 2001, when we submitted his rebuttal report. Upsher moved to limit his testimony, arguing that it was beyond fair rebuttal, outside of his expertise, and was improper as it amounted to legal conclusions.[16] This Court rejected Upsher's motion and ruled that Professor Bazerman could testify on rebuttal.[17] Undeterred by that order, Upsher rehashes two pages of argument about Professor Bazerman's initial rebuttal report. This effort to revisit Your Honor's ruling should be rejected.

Upsher also seeks to exclude all testimony related to a supplemental expert report of Professor Bazerman. This report is the subject of a pending motion by respondents, and in our response to that motion we have explained our basis for filing that supplemental report. As a threshold matter, we note that respondents suffered no prejudice from the filing of that supplemental report, as they will have had over two months to prepare for Professor Bazerman's testimony since receipt of the report.[18]

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offered in chief does not preclude its admission in rebuttal").

[16] Respondents' Joint Motion to Limit the Testimony of Max H. Bazerman (Jan. 3, 2002).

[17] Oral ruling on Respondents' Joint Motion to Limit the Testimony of Bazerman, January 22, 2002, Prehearing Conference at 164-166 (order allowed rebuttal testimony). Upsher incorrectly maintains that this Motion remains pending (Memo at 8).

[18] We submitted the supplemental expert report on January 14, 2002 to explain more fully issues raised during Professor Bazerman's deposition. Upsher's statement that it "never had the opportunity to examine Professor Bazerman" about this supplementation is simply not true. Motion at 8 n.2. Shortly after receiving respondents' motion to strike, we offered to arrange a date for an additional deposition of Professor Bazerman on his risk aversion opinions. This offer is clearly stated in

In his rebuttal testimony, Professor Bazerman will respond directly and specifically to new theories and evidence put forward by respondents during their defense case. For example respondents' experts testified that settlements are beneficial to society and that value creating side-transactions can help bring those settlements to fruition.[19] Professor Bazerman will directly rebut these facts and arguments, and respond that settlements are not always socially beneficial because they may come at the expense of third parties, such as consumers.

Finally, Professor Bazerman will respond to other specific pieces of new evidence and theories raised by respondents, such as their unsupported assumption that Schering was risk averse in its negotiations.[20]

2. Dr. Nelson Levy: The pivotal factual dispute in this case is whether Schering's $60 million non-contingent payment to Upsher-Smith was for the Niacor-SR license, or instead for the delayed September 1, 2001 entry date. During the case-in-chief, Dr. Levy provided his opinion that the $60 million payment by Schering to Upsher could not have been for the Niacor-SR license. He provided three independent bases for that opinion: (1) the $60 million non-contingent payment was

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our pleading opposing respondents' motion to strike Professor Bazerman's report. *See* Complaint Counsel's Opposition to Respondents' Joint Motion to Strike, at 3 (Jan. 31, 2002) ("complaint counsel offered to arrange a date for an additional limited deposition of Professor Bazerman on this issue"). Having rejected this offer out of hand, respondents should not now be heard to complain about their failure to depose Professor Bazerman. In contrast, when Schering submitted demonstratives for their experts Willig and Addanki, that made clear their trial testimony would go well beyond the scope of their reports, we agreed to depose them rather than seeking to exclude testimony of these new opinions.

[19] *See, e.g.*, Tr. at 12:2675, 2678 (Mnookin).

[20] *See, e.g.*, Tr. at 25:6094-95 (Addanki).

grossly excessive (and in fact, the largest such payment in Schering's history); (2) the due diligence conducted by Schering for Niacor-SR was strikingly superficial in relation to industry practices and Schering's own standards; and (3) the post-agreement conduct of both Schering and Upsher gave no indication that the parties were serious about developing and marketing Niacor-SR for sale in Europe.

Dr. Levy's rebuttal testimony is necessary because of the extensive new evidence and theories advanced by respondents' fact and expert witnesses trying to justify how Schering could make the largest non-contingent payment in its history without any meaningful due diligence. For example, rather than challenge the bases of Dr. Levy's opinion that Schering's due diligence for Niacor-SR was strikingly superficial, Schering witnesses testified quite surprisingly that the elaborate due diligence Schering normally conducts for in-licensing deals was somehow unnecessary for this product. According to Schering's Mr. Lauda, niacin was " rather straightforward in the marketplace," there was "very little risk of not being approved," and therefore Schering's cursory review of the product was sufficient.[21] Dr. Levy will rebut this new theory by providing his opinions regarding the state of knowledge in the pharmaceutical industry concerning sustained release niacin drugs and Schering's knowledge of such information at the time of its evaluation of Niacor-SR.

Another example of new evidence advanced by Schering concerns its challenge of Dr. Levy's analysis of non-contingent payments. As part of Mr. Lauda's testimony, Schering presented for the first time its theory that the size of the non-contingent payment by itself is not meaningful, but can only be analyzed in connection with certain other payments and expenditures.[22] Dr. Levy's rebuttal

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[21] Tr. at 19:4347-48 (Lauda); *See also* Tr. at 18:4137 (Audibert).

[22] Tr. at 19:4366-67 (Lauda); Tr. at 19:4443-84 (Lauda) (in camera).

testimony is necessary to explain why a company's commitment to make significant non-contingent payments in connection with an in-licensing transaction is fundamentally different than an agreement to make other types of payments and expenditures over which the company maintains some control.

Upsher does not seriously contend that Dr. Levy's rebuttal testimony would not "explain or rebut evidence"[23] presented by respondents. Rather, Upsher's argument to exclude testimony from Dr. Levy is based solely on its claim that Dr. Levy prepared a rebuttal report that commented only on the flawed analysis of Walter Bratic – an expert Upsher elected not to call. Motion at 8. This rationale seems to ignore that much of respondents' "evidence" about the Niacor-SR license came in through Schering fact witnesses – Lauda and Audibert – rather than with the four licensing experts respondents had designated to testify, of whom only one was called to the stand. The rules do not "require Commission counsel to anticipate through clairvoyance respondents' evidence."[24] For this reason, Dr. Levy is entitled to "disprove or contradict the evidence presented" by respondents so long as his testimony is based on the opinions of which respondents are aware.[25]

3. James Egan: James Egan is the former Director of Licensing at Searle & Company. Mr. Egan's rebuttal testimony is necessary to correct testimony offered by Upsher that his company – Searle – was interested in licensing the Niacor-SR product, based on a single meeting it had with Searle; and to address Schering and Upsher testimony to the effect that Niacor and Niaspan were of similar value.

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[23] *Tejada*, 956 F.2d at 1266.

[24] *Modern Methods, Inc.*, 60 F.T.C. at 331.

[25] *See DeMarines v. KLM Royal Dutch Airlines*, 580 F.2d 1193 (3d. Cir. 1978).

At least three Upsher witnesses testified about the Searle-Upsher meeting of May 28, 1997 – Mark Halvorsen, Lori Freese, and Greg Brown,[26] with Halvorsen and Freese testifying that Searle was interested in Upsher's Niacor-SR product. Halvorsen went so far as to erroneously state that the reason Searle was not immediately interested in the product was because it was developing another product.[27] In contrast, Mr. Egan, who participated in the meeting, on behalf of Searle will directly rebut the testimony of these witnesses by explaining the reasons for Searle's lack of interest in a Niacor-SR license.

Second, a multitude of Upsher and Schering witnesses have testified that they believed Kos's Niaspan and Upsher's Niacor were of equivalent value.[28] Dr. Kerr, for example, based much of his opinion regarding the $60 million payment on the assumption that Niacor and Niaspan were equivalent products.[29] Mr. Troup stated that he based his $60 million demand to Schering to settle the patent litigation on Kos's expectations about Niaspan sales.[30] As a representative of one of the only other companies besides Schering to have evaluated both products, Mr. Egan's testimony on the issues of Searle's interest in the Niaspan product, Searle's methods for evaluating opportunities, Searle's

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[26] Tr. at 17:3965-70 (Halvorsen); 21:4977-81 (Freese); 14:3173-77 (Brown).

[27] *See* Tr. at 17:3969-70 (Halvorsen); 21:4980-81 (Freese).

[28] *See, e.g,* Tr. at 16:3662-63 (Horovitz); 17:3947-48 (Halvorsen); 19:4351 (Lauda); 21:5085-86 (Kralovec); 23:5441-47 (Troup).

[29] Tr. at 26:6292-6325; 28:6824-26 (Kerr).

[30] Tr. at 23:5444-45, 5447 (Troup).

negotiations with Kos for that product, and Searle's belief that Niaspan was superior to Niacor-SR, are matters directly relevant to rebutting the claims of Upsher and Schering.[31]

4. Mike Valazza: Mike Valazza is the vice-president of business development for IPC. His testimony will directly rebut testimony from Upsher witnesses regarding his company's capabilities to manufacture certain ingredients for Upsher's generic version of K-Dur 20.

Complaint counsel had no reason to call Mr. Valazza as a witness during its case-in-chief, because his testimony was unnecessary for our prima facie case. Now, by contrast, Mr. Valazza's testimony is necessary to rebut testimony from two Upsher employees about his company's manufacturing capabilities. Scott Gould, an Upsher witness, testified no less than seven times that IPC was unable to manufacture the quantities of certain ingredients that Upsher needed to launch its product.[32] He went on at length about the need to expand IPCs' capabilities, the equipment necessary for this expansion, and the overall time and costs necessary for the expansion.[33] Ian Troup also testified that IPC could not produce the quantities Upsher needed.[34] IPC's alleged lack of readiness to manufacture the quantities Upsher needed, and the steps that had to be taken to rectify this alleged

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[31] Contrary to Upsher's claim, we do not seek to present Mr. Egan as a surrogate expert on licensing or due diligence; rather, in order to provide the foundation for his testimony regarding Searle's relative interest in Niacor-SR and Niaspan, Mr. Egan will need to give information on Searle's internal procedures for evaluating these two products for licensing.

[32] Tr. at 21:5116, 5118, 5124, 5126, 5128, 5137 (Gould).

[33] Tr. at 21:5128-60 (Gould).

[34] Tr. at 23:5484 (Troup).

situation, were new facts raised by Upsher to support its defense. Mr. Valazza must be permitted to testify as to IPC's actual manufacturing capabilities at the relevant times.

5. Kos Witnesses (Daniel Bell and Mukesh Patel): Complaint counsel have designated two people from Kos Pharmaceuticals as rebuttal witnesses: Daniel Bell, the President and Chief Executive Officer of Kos, and Mukesh Patel, who was Vice-President of Licensing for Kos at the time of the negotiations with Schering for a potential license of Kos's Niaspan product. In its defense case, Schering put forward new facts and arguments directly related to Kos. Kos's perspective on these issues, which Mr. Bell and Mr. Patel will provide, is highly probative and proper rebuttal testimony.[35]

For example, Schering has argued that the negotiations between Schering and Kos broke down because of Kos's unreasonable expectations for a licensing deal. Specifically, Mr. Audibert and Mr. Russo testified that Kos's request that Schering position Niaspan as the primary product for detailing was unreasonable, and that Schering would not accommodate that request.[36] Although the fact of these negotiations was discussed in the case-in-chief, the reason for their breakdown was not. The testimony of Mr. Patel and Mr. Bell will refute Schering's testimony by explaining Kos's expectations of Schering and why these expectations were reasonable. Mr. Patel, who was directly involved in the negotiations with Schering, will also provide particularized evidence concerning those discussions, including the fact that the duration of primary detailing would have lasted only a few years.

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[35] It is necessary to call both Mr. Bell and Mr. Patel because each has unique evidence to offer.

[36] *See* Tr. at 18:4106-07, 4111-12 (Audibert); 15:3450-51 (Russo).

Another example of new evidence advanced by Schering concerns assertions that since niacin was a well-known compound, extensive due diligence was not necessary to evaluate a niacin-based drug such as Upsher's Niacor-SR. In particular, both Mr. Audibert and Mr. Lauda testified that the additional studies the FDA would have required Upsher to complete as part of an NDA filing were routine, and neither costly nor time-consuming.[37] Mr. Patel and Mr. Bell will rebut those assertions, explaining that Kos completed a substantial number of pharmacokinetic studies of Niaspan, and that the FDA closely scrutinized them. Further, Mr. Bell will testify that Kos devoted a significant amount of time and resources to the development of Niaspan because very little was known about the mechanics of the compound.

A third example of new evidence from Schering that the Kos witnesses will properly rebut concerns the lower-than-expected sales of Niaspan in the U.S. According to Schering, these lower-than-expected U.S. sales had a negative impact on the potential European sales of Niacor-SR. This, in turn, purportedly contributed to Schering's and Upsher's abandonment of efforts to sell Niacor-Sr in Europe.[38] Although this topic bears some relation to an issue raised in our case-in-chief (*i.e.*, the license value of Niacor-SR in Europe), it does so in a wholly different factual context, as it concerns Schering's claims about why the product was abandoned, a fact first raised in the defense case. Mr. Patel will testify that market conditions in Europe vary significantly from those in the United States, and that, as a result, U.S. sales of a product cannot be used as the ultimate measure of how well a product will sell in Europe.

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[37] *See* Tr. 18:4134-35 (Audibert); 19:4418, 4421-23 (Lauda).

[38] Tr. at 18:4143-45 (Audibert).

CONCLUSION

For the reasons discussed above, Upsher's motion should be denied in its entirety.

Respectfully submitted,

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Dated: March 13, 2002