UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

UPSHER-SMITH'S OPPOSITION TO COMPLAINT COUNSEL'S MOTION *IN LIMINE* TO EXCLUDE EXPERT TESTIMONY OF ROBERT POLLOCK

Complaint Counsel accurately set forth the prevailing standards under *Daubert, Kumho Tire*, Rule 702 of the Federal Rules of Evidence, and Rule 3.43 of the Commission's Rules of Practice. While these standards doom several of Complaint Counsel's experts, they do not provide grounds for the exclusion of any expert testimony by Robert Pollock. As explained below, Mr. Pollock is qualified "by knowledge, skill, experience, training, or education," and he offers "reliable" opinions that will "assist the trier of fact to understand the evidence or to determine a fact in issue . . . ." Fed. R. Evid. 702.

ARGUMENT

Complaint Counsel's challenge to Mr. Pollock is based on a flawed premise. Contrary to Complaint Counsel's assumption, Mr. Pollock is not proffered as an expert on law. He is proffered as an expert on FDA policy and prevailing industry perceptions of that policy at times relevant to this case. This is perfectly proper expert testimony and relevant here to corroborate

the fact testimony of Upsher-Smith witnesses as to their state of mind in June 1997. And Mr. Pollock is eminently qualified to give such testimony.

I. MR. POLLOCK IS WELL-QUALIFIED TO PROVIDE OPINIONS ON FDA POLICIES AND PREVAILING INDUSTRY PERCEPTIONS OF FDA POLICIES

Mr. Pollock spent ten years at the FDA. At the FDA, Mr. Pollock had direct involvement in drafting regulations implementing Hatch-Waxman including participating in the drafting of the 1992 and 1994 implementing regulations. Pollock Dep. at 46:3-9, 54:12-17. In his last assignment, from November 1993 to January 1995, he was the Acting Deputy Director of the FDA's Office of Generic Drugs, the office that approves all ANDAs. *Id.* at 54:8-11. As Acting Deputy Director, he was responsible for "overseeing the review and approval process of all generic drugs approved for marketing in the United States." Pollock Rep. at 1. His office "worked very closely with the new drug evaluation divisions because the requirements for approval of generic drugs actually impacted on the approval requirements for some of the new drug applications . . . ." Pollock Dep. at 66:9-16.

After leaving the FDA, Mr. Pollock entered the private sector as a consultant on FDA matters. Since 1995 he has been associated with Lachman Consultant Services, Inc., a leading FDA consultancy. He has been a vice president since 1998. His responsibilities at Lachman Consulting Services include "providing expert technical advice to domestic and international clients regarding U.S. Food and Drug Administration . . . regulations." Pollock Rep. at 1. This has been his full-time employment since leaving the FDA. Approximately 30 percent of his time is spent on Hatch-Waxman and 180-day exclusivity issues, the exact same issues he addresses in his expert testimony. Pollock Dep. at 33:23-34:3. Thus, Mr. Pollock has worked on FDA

regulatory matters exclusively for nearly 17 years, in the public and private sector, with much of that time focused directly upon issues raised in this proceeding.[1]

Because of his experience, Mr. Pollock can provide valuable expert testimony. During his tenure at the FDA he became expert in the internal review of ANDA applications and FDA recognition of 180-day exclusivity provisions. He is the only current or former FDA official who will testify at trial. During the time of the Schering/Upsher-Smith settlement, he was advising members of the pharmaceutical industry on ANDA and exclusivity regulations. Mr. Pollock has the unique perspective of someone who intimately understands the FDA's policies regarding Hatch-Waxman and also understands the pharmaceutical industry's view of those policies at the time of the Schering/Upsher-Smith settlement first hand.

Upsher-Smith retained Mr. Pollock in response to Complaint Counsel's designation of Joel Hoffman as an FDA/Hatch-Waxman expert. Mr. Hoffman is simply a practicing lawyer who counsels clients on FDA law. Counsel for Upsher-Smith, not wanting to present legal argument in the guise of expert testimony, consciously elected to retain a non-lawyer FDA/Hatch-Waxman regulatory expert. And Mr. Pollock is one of the best in the field. Complaint Counsel misapprehend Mr. Pollock's role in suggesting that his lack of a law degree undermines his expert opinions.

In describing the relevant credentials of their own expert, Joel Hoffman, Complaint Counsel inadvertently confirm the relevance of Mr. Pollock's credentials. Complaint Counsel assert that Mr. Hoffman has counseled clients on FDA regulatory law "for nearly 30 years."

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[1] Mr. Pollock's on-point experience during the time relevant to this proceeding stands in stark contrast to the experience of Complaint Counsel's licensing "expert" Nelson Levy. Levy's minimal experience in licensing occurred in the wrong geographic market and pre-dates by years the June 1997 transactions at issue here.

Mem. at 9. Mr. Hoffman's pre-1997 experience cannot be any more relevant than Mr. Pollock's. Complaint Counsel also assert that Mr. Hoffman has counseled clients on the Hatch-Waxman Act "since its enactment in 1984." Mem. at 9. Again, this pre-1997 experience can be no more relevant than Mr. Pollock's.

At bottom, Complaint Counsel's only quarrel with Mr. Pollock's credentials is his lack of a law degree. But, as Complaint Counsel admit in their Memorandum In Support Of Complaint Counsel's Motion To Limit Or Exclude Duplicative And Improper Expert Witness Testimony — filed the very same day as their present motion — it is ***improper*** for an expert to tell this Court how to interpret the law. *Specht v. Jensen*, 853 F.2d 805, 807 (10th Cir. 1988) (en banc) ("[I]t is axiomatic that the judge is the sole arbiter of the law and its applicability . . . ."); *see, e.g., In re Initial Pub. Offering Sec. Litig.*, No. 21 MC 92 (SAS), 2001 U.S. Dist. LEXIS 18116, at *7-8 (S.D.N.Y. Nov. 7, 2001) ("[E]very circuit has explicitly held that experts may not invade the court's province by testifying on issues of law.") (collecting cases). Therefore, a law degree is not relevant as an expert is forbidden from providing a legal opinion.

By boasting of Joel Hoffman's legal credentials, Complaint Counsel seem to be unwittingly admitting that Mr. Hoffman is providing improper expert testimony. This same principle also undermines the intended testimony of Complaint Counsel's rebuttal expert Max H. Bazerman who intends to instruct this Court on how antitrust law ought to be developed. *See* Respondents' Joint Motion To Limit The Testimony Of Max H. Bazerman at 6. Complaint Counsel's contention that Mr. Pollock cannot testify as to the state of the law is beside the point as he is not attempting to testify "for the purpose of proving what the law is; the declaration of controlling law must come from the court. Rather, [his testimony is] admissible as it relates to [Upsher-Smith's] understanding and resulting state of mind." *United States v. Cavin*, 39 F.3d 1299, 1309 (5th Cir. 1994).

Mr. Pollock's personal experience as an FDA official, and the insight that experience affords, is a much more relevant credential. And it is one that Mr. Hoffman does not possess.

II. MR. POLLOCK'S OPINIONS ARE RELIABLE AS HE RELIED ON AUTHORITATIVE DOCUMENTS AND HIS OPINIONS ARE CONSISTENT WITH OTHERS IN THE FIELD

Complaint Counsel's challenge to the "reliability" of Mr. Pollock's opinions is also off the mark. Mr. Pollock expressly relies upon authoritative documents from the relevant 1997 timeframe, including FDA guidance letters, court decisions, and "Pink Sheet" publications that are relied on by members of the pharmaceutical industry. He also expressly relies upon his "professional recollection, knowledge and experience." Pollock Rep. at 4. His opinions are verifiable by examining the documents he cites and by consulting other experts in the field. *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149 (1999) (holding that expert testimony must have "a reliable basis in the knowledge and experience of the relevant discipline") (internal quotations omitted). The fact that Mr. Pollock's opinions are largely consistent with those of Complaint Counsel's expert, Hoffman, and Schering's expert, Peter O. Safir, confirms that Mr. Pollock's opinions are reliable and neither subjective nor controversial.

III. MR. POLLOCK'S TESTIMONY IS RELEVANT TO THE PROCEEDINGS AND WILL ASSIST THE TRIER OF FACT

Mr. Pollock was asked to opine, based on his experience as an FDA official and consultant, on "the state of 180-day exclusivity rights . . . and the ***industry perceptions*** as to those rights, at the time of the agreement between Schering-Plough and Upsher-Smith . . . ." Pollock Rep. at 3 (emphasis added). What the industry perceptions of the Hatch-Waxman 180-day exclusivity rights were in June 1997 is of primary importance in this case.

The Complaint alleges that Upsher-Smith "specifically intended" to maintain Schering's alleged monopoly in the potassium supplement market. Compl. ¶ 71. According to the complaint, the Schering/Upsher-Smith settlement agreement maintained a Schering monopoly by

delaying the start of Upsher-Smith's 180-day exclusivity period until September 2001, thereby preventing other generic competitors from entering the market until March 2002. *Id.* ¶¶ 47, 66. In order to "specifically intend[]" to maintain Schering's monopoly, Upsher-Smith would have had to know it would be granted 180-day exclusivity rights upon settlement. *See, e.g., AFL-CIO v. Fed. Election Comm'n*, 628 F.2d 97, 102 (D.C. Cir. 1980) ("It is clear that uncertainty as to the meaning of the law can be considered in assessing the element of willfulness in a violation of the law."). Thus, the then-prevailing perception as to 180-day exclusivity under Hatch-Waxman is of singular importance in this proceeding.

At trial, Upsher-Smith officers will testify that in June 1997 they did not contemplate that Upsher-Smith would have 180-day exclusivity upon a settlement with Schering. Mr. Pollock's expert testimony will support this fact testimony by establishing that there was no reasonable basis in June 1997 for Upsher-Smith, or anyone else in the pharmaceutical industry, to believe that the FDA would grant 180-day exclusivity to a settling first ANDA filer. As Mr. Pollock explained in his report, even "a fully informed settling first filer would have had little or no reason ***to believe*** that it would enjoy such exclusivity." Pollock Rep. at 4 (emphasis added).

It is fundamental that "where the element of willfulness is critical to the defense, the defendant is entitled to wide latitude in the introduction of evidence tending to show lack of intent." *United States v. Garber*, 607 F.2d 92, 99 (5th Cir. 1979) (en banc). In *Garber*, the Fifth Circuit held that it was reversible error for the trial court to refuse to permit an accountant/former revenue agent to provide expert testimony that it was unclear whether income derived from a sale of blood plasma was taxable. *See id.* The Fifth Circuit held that such expert testimony was competent perception testimony rather than improper legal opinion. *See id.* 99-100. Likewise here, Mr. Pollock, an FDA consultant and former FDA regulator, seeks to testify that there was little or no reason for Upsher-Smith to believe that it would be entitled to 180-day exclusivity

upon the June 1997 settlement. *See Cavin*, 39 F.3d at 1309 ("the unresolved nature of the law is relevant to show that the defendant may not have been aware of . . . liability") (quoting *Garber*, 607 F.2d at 98-99).

Complaint Counsel question only one aspect of Mr. Pollock's opinion addressing Hatch-Waxman. Mem. at 12. They question Mr. Pollock's statement that *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128 (D.D.C. 1997) "was of little guidance to an ANDA filer settling its patent lawsuit." *Id.* This statement, which reflects Mr. Pollock's focus on industry perception, is clearly well-grounded. The *Mova* case did not involve a settling ANDA filer; therefore its applicability to that circumstance was not at all clear. Notably, Complaint Counsel's Hatch-Waxman expert, Joel Hoffman, agrees. In his report, Hoffman writes that in *Mova* "the D.C. district court granted a preliminary injunction against application of the FDA 'successful defense' regulation to the first Paragraph IV ANDA submitter in the case before it, on the ground that the regulation was inconsistent with the 180-day exclusivity statute and therefore invalid. The court did not, however, enjoin application of the regulation in matters other than the one before it." Hoffman Rep. at 11. Mr. Hoffman concludes: "On June 17, 1997, therefore, it was impossible to say with any confidence whether Upsher was or was not entitled as of that date to a 180-day exclusivity period." Hoffman Rep. at 12.

Complaint Counsel also misstate Mr. Pollock's testimony regarding the competitive nature of the Schering/Upsher-Smith agreement, by again accusing him of offering a legal opinion and this time adding that he is offering an impermissible opinion as an antitrust economist. In fact, Mr. Pollock will testify, based upon his experience as an FDA regulator and industry consultant, that "the settlement agreement actually ***appears*** to be pro-competitive in nature since it assured that a generic potassium chloride extended-release tablet equivalent to the innovator's would be on the market as early as September 1, 2001, rather than at patent expiry on

September 5, 2006." Pollock Rep. at 8 (emphasis added). Mr. Pollock's testimony on this point will support the testimony of Upsher-Smith witnesses that they perceived the settlement as a procompetitive agreement.

His opinion is, again, relevant as an opinion regarding the appearance of the agreement to a member of the pharmaceutical industry. If the agreement ***appeared*** to be procompetitive — *i.e.*, a member of the pharmaceutical industry would not have thought it aided any firm's monopoly — it would also have been impossible for Upsher-Smith to specifically intend to cause an anticompetitive result. *See* Compl. ¶ 71. Mr. Pollock expressly disclaimed that his opinion represented a legal or economic opinion; as with his other opinions, Mr. Pollock was addressing industry perception.

Again, it is axiomatic that an expert cannot opine as to a conclusion of law. *See Nieves-Villanueva v. Soto-Rivera*, 133 F.3d 92, 100 (1st Cir. 1997) (excluding expert legal opinion "because the judge's expert knowledge of the law makes any such assistance at best cumulative, and at worst prejudicial"). But, if the appearance of an agreement is an issue, *i.e.*, whether a member of the pharmaceutical industry would have believed it to be procompetitive as opposed to whether it was in fact procompetitive, expert opinion is not only proper, but also necessary.

Finally, Complaint Counsel faults Mr. Pollock for not having formal medical training and for not reviewing the detailed chemistry of Niacor SR in reaching his opinion that Niacor SR was likely to win FDA approval. Again, Complaint Counsel misconstrues Mr. Pollock's testimony. Mr. Pollock is not purporting to give a medical opinion, but rather an opinion that based on the correspondence between Upsher-Smith and the FDA, there would not appear to be any barriers to approval. Mr. Pollock's FDA experience qualifies him to make this opinion, the opinion is "reliable" and could be verified by other experts in the field, and it is relevant to whether Upsher-Smith could have had the specific intent to violate the antitrust laws. This testimony is crucial,

because it rebuts the charge that Niacor SR was worthless and that the license of Niacor SR was a sham. This testimony supports the testimony of Upsher-Smith fact witnesses who will state that they had the highest hopes for Niacor SR in June 1997.

Notably, Complaint Counsel does not even challenge the propriety of Mr. Pollock's remaining opinion that no other pharmaceutical company was in fact kept off the market by Upsher-Smith's putative 180-day exclusivity. As will be established at trial, this unchallenged opinion drives a stake through the heart of Complaint Counsel's contention that the June 1997 agreement delayed entry of other potential generic manufacturers.

CONCLUSION

For all of the foregoing reasons, Complaint Counsel's Motion *In Limine* To Exclude Expert Testimony Of Robert Pollock should be denied.

Dated: January 10, 2002

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of January 2002 I caused an original, one paper copy and an electronic copy of Upsher-Smith's Opposition To Complaint Counsel's Motion *In Limine* To Exclude Expert Testimony Of Robert Pollock to be filed with the Secretary of the Commission, and that two paper copies were served by hand upon:

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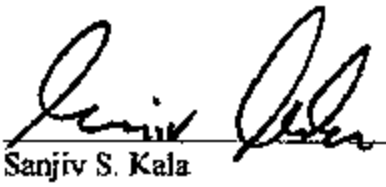

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