UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

FEDERAL TRADE COMMISSION
RECEIVED DOCUMENTS
JAN 4 2002
SECRETARY

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

ORDER SHORTENING TIMES FOR RESPONSES

On January 4, 2002, Complaint Counsel filed a motion for an extension of time for filing its responses to Respondents' motions *in limine*. Complaint Counsel's motion represents that it conferred with Respondents but that they were unable to reach an agreement for an extension of time to respond to the motions. Pursuant to Section 3.22(c) of the Commission's Rules of Practice, 16 C.F.R. § 3.22(c) and due to the approaching trial date, to the extent Respondents intend to oppose Complaint Counsel's motion for an extension of time, Respondents must file their oppositions by 1:00 p.m. on Tuesday, January 8, 2002.

On January 4, 2002, Respondent Schering-Plough Corporation ("Schering") filed a motion for an extension of time for filing its motion *in limine* to exclude the testimony of Banakar and Adelman. The Scheduling Order requires motions *in limine* to be filed by January 3, 2002. According to the motion, Schering attempted to file the motion on January 3, 2002, but arrived at the Office of the Secretary four minutes passed the filing deadline. Schering does not indicate whether its motion for an extension of time is opposed by Complaint Counsel. Pursuant to Section 3.22(c) of the Commission's Rules of Practice, 16 C.F.R. § 3.22(c) and due to the approaching trial date, to the extent Complaint Counsel intends to oppose Schering's motion for an extension of time, Complaint Counsel must file its opposition by 1:00 p.m. on Tuesday, January 8, 2002.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Date: January 4, 2002

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

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

ORDER GRANTING MOTION OF MERCK-MEDCO MANAGED CARE FOR EXTENSION OF TIME IN WHICH TO FILE MOTION FOR *IN CAMERA* TREATMENT OF PROPOSED TRIAL EXHIBITS

On December 31, 2001, third party Merck-Medco Managed Care, L.L.P. ("Merck-Medco") filed a motion for extension of time in which to file a motion for *in camera* treatment o certain documents which Respondent Upsher-Smith Laboratories, Inc. ("Upsher-Smith") has listed as proposed trial exhibits. Upsher-Smith does not oppose Merck-Medco's motion for an extension of time.

Merck-Medco's motion is hereby GRANTED. Merck-Medco has until January 11, 2002 to file its motion for *in camera* treatment. Any opposition to Merck-Medco's motion for *in camera* treatment is due on January 18, 2002.

ORDERED:

D. Michael Chappell
Administrative Law Judge

Date: January 4, 2002.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

FEDERAL TRADE COMMISSION
RECEIVED DOCUMENTS
JAN 7 2002
SECRETARY

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 MOTION FOR THE ISSUANCE OF SUBPOENAS *AD TESTIFICANDUM*

Pursuant to Rule 3.34(a)(2) of the Federal Trade Commission's Rules of Practice, complaint counsel move for an Order authorizing the issuance of a nine subpoenas *ad testificandum* to be issued to [redacted].

Each of these individuals' testimony is reasonably relevant to complaint counsel's prosecution of this matter and thus satisfies the conditions under Rule 3.34(a)(2) for the issuance of a subpoena *ad testificandum* to give testimony at an adjudicative hearing. Each of these individuals was listed on Complaint Counsel's Preliminary Witness List and is currently on Complaint Counsel's Final Witness List. A brief description of each individual's position and relevance to complaint counsel's case follows.

[redacted] We expect [redacted] to testify generally about [redacted] prescription drug coverage program, contracting, and cost-containment strategies, and, in particular, [redacted] selection of prescription potassium supplements for its formulary. We also expect [redacted] to testify about the use of potassium chloride in treatment.

[redacted] We expect [redacted] to testify generally about [redacted] prescription drug coverage program, contracting, and cost-containment strategies, and, in particular, [redacted] selection of prescription potassium supplements for its formulary. We also expect [redacted] to testify about the use of potassium chloride in treatment.

[redacted] We expect [redacted] to testify generally about the impact that a generic product has on a branded product's revenues and market share. [redacted] is also expected to testify about the status of [redacted] ANDA for an AB-rated generic version of Schering's K-Dur 20 product and [redacted] plans for marketing its product.

[redacted] We expect [redacted] to testify generally about [redacted] contact with Upsher-Smith Laboratories, Inc. ("Upsher") regarding Upsher's Klor Con 20mEq product.

[redacted]

[redacted]. We expect [redacted] to testify about [redacted] procedures for evaluating products for licensing. In addition, [redacted] may testify about the negotiations between Upsher and [redacted] regarding Upsher's Niacor-SR product and about the negotiations between and [redacted] regarding [redacted] product.

[redacted] We expect [redacted] to testify generally about the negotiations between [redacted] and Schering-Plough Corporation ("Schering") and other pharmaceutical companies regarding [redacted] product and about issues related to marketing [redacted] in Europe. [redacted] is also expected to testify about the cross-licensing agreement between Upsher and [redacted] related to patents for extended-release niacin.

[redacted]. We expect [redacted] to testify generally about the negotiations between [redacted] and Schering regarding [redacted] product and about issues related to marketing [redacted] in Europe.

[redacted] We expect [redacted] to testify about the patent infringement suit and settlement reached between AHP and Schering over the '743 patent.

[redacted] We expect [redacted] to testify generally about the procedure for evaluating licensing agreements at ESI and specifically about the negotiations between Schering and ESI over buspirone and enalapril. We also expect [redacted] to testify about the settlement negotiations

between Schering and ESI involving the litigation over the '743 patent. In addition, we expect ********** to testify generally about the impact that a generic product has on a branded product's revenues and market share and specifically about ESI's expectation of the impact that its AB-rated generic product would have on K-Dur 20.

For the foregoing reasons, each of the individuals for whom complaint counsel seek a subpoena *ad testificandum* is relevant to an element in either complaint counsel's case-in-chief or case-in-rebuttal. Complaint counsel thus respectfully request that its motion be granted in all respects.

Dated: January 7, 2001

Respectfully Submitted,

Karen G. Bokat
Robin L. Moore
Andrew S. Ginsburg
Complaint Counsel

CERTIFICATE OF SERVICE

I, Andrew S. Ginsburg, hereby certify that on January 7, 2001:

I caused two copies of the public version of Complaint Counsel's Motion For The Issuance Of Subpoenas *Ad Testificandum* to be served upon the following person by hand delivery-

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

I caused one original and one copy of the public version of Complaint Counsel's Motion For The Issuance Of Subpoenas *Ad Testificandum* to be served upon the following person by hand delivery and one copy to be served by electronic mail-

Office of the Secretary
Federal Trade Commission
Room H-159
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

I caused copies of the public version of Complaint Counsel's Motion For The Issuance Of Subpoenas *Ad Testificandum* to be served upon the following persons by electronic mail and Federal Express-

Laura S. Shores, Esq.
Howrey Simon Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2402

Christopher M. Curran, Esq.
White & Case LLP
601 13th Street, N.W.
Washington, D.C. 20005

Andrew S. Ginsburg

United States of America
Federal Trade Commission

In the Matter of MSC Software Corporation, a corporation.	)	Dkt. No. 9299

Notice of Withdrawal of Motion of DaimlerChrysler Corporation to Limit Subpoena Duces Tecum

To: The Honorable D. Michael Chappell
Administrative Law Judge

DaimlerChrysler Corporation, through its attorneys, withdraws its Motion to Limit Subpoena Duces Tecum, filed on December 12, 2001, based on the agreement of its attorneys and Complaint Counsel.

Respectfully submitted,

Allan M. Huss, Senior Staff Counsel
DaimlerChrysler Corporation
1000 Chrysler Drive, CIMS 485-13-65
Auburn Hills, Michigan 48326-2766
(248)-512-4126
Fax: (248)-512-4202

Dated: January 7, 2002

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
MSC.SOFTWARE CORPORATION, a corporation.	)	Docket No. 9299

SUPPLEMENT TO COMPLAINT COUNSEL'S MOTION TO COMPEL COMPLIANCE WITH SUBPOENAS AD TESTIFICANDUM AND DUCES TECUM

There is added reason for this Court to enter an order compelling Respondent's current and former employees to appear for depositions as originally scheduled. On Saturday, January 5, 2002, by a telephone message from its counsel, Respondent canceled three of Complaint Counsel's scheduled depositions set for Tuesday, Wednesday, and Thursday, January 8, 9, and 10, 2002. (Ex.A, Declaration of P. Abbott McCartney). The cancellations were confirmed by letter from Respondent's counsel today, January 7. (Ex. B, Letter of Marimichael O. Skubel). The scheduled depositions involve two current employees of Respondent, Messrs. Todd Brown and Robert Louwers, and one former employee, Mr. Thomas Curry. The cancellation followed Complaint Counsel's January 3 deposition of David Beer, another current employee of Respondent.

Respondent's cancellation of these three depositions overturns its prior commitment to this Court that it would proceed with these and other scheduled depositions. The cancellation is added reason why Complaint Counsel's December 17, 2001, motion is not moot and why the Court should enter an order compelling these and the remaining scheduled witnesses to appear for their depositions as agreed by Respondent.

Respondent's stated explanation for its decision to withdraw the witnesses was its claimed need for more time to "process" recently produced materials. Its purported reasons are unrelated to any emergency or unforeseen scheduling conflict raised by any of the subpoenaed witnesses. Respondent's justification is not acceptable. The Commission's own rules state that discovery by both sides should proceed simultaneously.[1] Respondent is attempting to unilaterally delay the trial date by delaying the depositions of its current and former employees and by failing to produce documents in response to Complaint Counsel's document request.

Respondent has had over forty days to prepare for these depositions. Throughout, Respondent has had access to its current and former employees and to its own documents. Additionally, Compliant Counsel turned over to Respondent on December 11, 2001, most of the third-party materials received in response to Commission investigative subpoenas and remaining materials on December 21, 2001. On January 2, 2002, Complaint Counsel supplied verbatim statements of witnesses identified on Complaint Counsel's December 17, 2001, preliminary witness list. Complaint Counsel has also promptly turned over to Respondent documents produced by the Lockheed Martin Corporation and the Boeing Company in response to subpoenas *duces tecum* issued on behalf of Complaint Counsel to those firms.

In today's letter, Respondent's counsel accuses Complaint Counsel of "sandbag[ging] our witnesses" by using recently-received third party documents to examine MSC's employee Mr. Beer at his deposition on Thursday last week. In fact, however, the only documents used in

---

[1] "The parties shall, to the greatest extent practicable, conduct discovery simultaneously; the fact that a party is conducting discovery shall not operate to delay any other party's discovery." 16 C.F.R. § 3.11.

the examination of Mr. Beer were MSC customer contracts or other documents prepared by Mr. Beer himself or by others at MSC and with which Mr. Beer was familiar in his capacity as a sales representative for MSC. Though the documents came from the files of MSC customers, and not MSC itself, there was absolutely no impropriety in using them in the deposition. In fact, Complaint Counsel would have preferred to examine Mr. Beer using copies of the same documents from MSC's files, but was unable to do so because they have never been produced to Complaint Counsel by MSC, either in the investigative stage of the case or in response to the document request that has been outstanding since before Thanksgiving.[2]

Complaint Counsel request that the Court grant our Motion to Compel Compliance with these Subpoenas *Ad Testificandum* and *Duces Tecum* for the reasons set forth above and in Complaint Counsel's December 17, 2001, Response to Respondent MSC.Software Corp.'s

[2] It is still the case, as recited in Complaint Counsel's pending Motion to Compel Compliance with the document request, that not a single responsive document has yet been produced by MSC in response to the document request.

Motion to Quash Subpoenas *Ad Testificandum* and Complaint Counsel's Motion to Compel Compliance with Subpoenas *Ad Testificandum* and *Duces Tecum*.

Respectfully Submitted,

P. Abbott McCartney

P. Abbott McCartney
Peggy D. Bayer
Kent E. Cox
Karen A. Mills
Patrick J. Roach
Counsel Supporting the Complaint
Bureau of Competition
Federal Trade Commission
Washington, D.C. 20580
(202) 326-2695
Facsimile (202) 326-3496

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
MSC.SOFTWARE CORPORATION, a corporation.	)	Docket No. 9299

DECLARATION OF P. ABBOTT McCARTNEY

I, P. Abbott McCartney, make the following statement:

1. I am an attorney for the Federal Trade Commission. I serve as Complaint Counsel in *MSC.Software Corporation*, Docket No. 9299.

2. On January 5, 2002, I picked my phone mail messages. There was a message from counsel for Respondent, Marimichael O. Skubel, left at 1:00 p.m. on January 5, 2002, cancelling Complaint Counsel's depositions of Messrs. Curry, Brown, and Louwers, scheduled for January 8, 9, and 10, 2002, respectively.

3. In her message, Ms. Skubel stated "we are going to have to cancel Curry, Louwers, and Brown for next week" and said that the reason for the cancellations was counsel's need, before they prepare the witnesses for their depositions, to process documents and statements that were provided by Complaint Counsel in discovery .

4. At about 4:45 p.m. on January 5, 2002, I left a message with counsel for Respondent, Marimichael O. Skubel, that we expect the three witnesses to appear at the scheduled times and dates for their depositions.

5. On Monday, January 7, 2002, I received by fax a letter from Ms. Skubel confirming the cancellation of these depositions.

Executed on January 7, 2002

P. Abbott McCartney

P. Abbott McCartney

Exhibit B

KIRKLAND & ELLIS
PARTNERSHIPS INCLUDING PROFESSIONAL CORPORATIONS

655 Fifteenth Street, N.W.
Washington, D.C. 20005

202 879-5000

Facsimile:
202 879-5200

Marimichael O Skubel
To Call Writer Directly:
(202) 879-5034
Marimichael_skubel@dc.kirkland.com

January 7, 2002

Via Facsimile

P. Abbott McCartney, Esq.
Federal Trade Commission
Bureau of Competition
601 Pennsylvania Avenue, N.W.
Washington, DC 20580

Subject: MSC.Software Inc., Docket No. 9299

Dear Abbott:

This letter memorializes the message I left on your voice mail that Messrs. Curry, Brown, and Louwers will not be available for depositions this week. As my voice mail of January 5, 2002 stated, it is not fair to hold these depositions at this time. As was evident in Mr. Beer's deposition on January 3, Complaint Counsel is in possession of a significant number of third-party documents that were provided to MSC only days ago.

We believe it was improper for Complaint Counsel to review these documents and use them to examine Mr. Beer without affording MSC timely access to these documents. In addition, the third-party verbatim statements, long withheld by Complaint Counsel, are critical to the preparation of MSC's defense. Complaint Counsel cannot continue to sandbag our witnesses in this manner. Indeed, Complaint Counsel's conduct becomes even more egregious in light of its failure to respond adequately to MSC's interrogatories. Because Complaint Counsel has chosen to hide the ball rather than provide the information it claims supports its case, MSC's ability to prepare for these depositions has been severely hampered.

We will review the substantial volume of documents that have just been produced and the twenty verbatim transcripts and declarations Complaint Counsel has withheld until last week, and we will prepare MSC's witnesses accordingly, consistent with our obligations under the Protective Order.

Because Complaint Counsel has had the opportunity to seek deposition testimony during the investigation stage, there is no prejudice to a short delay. On the other hand, holding the

depositions this week, without affording MSC adequate time to prepare, would be highly prejudicial to MSC. We are, of course, willing to work with you to reschedule these depositions and will contact you this week to discuss logistics.

Respectfully,

Marimichael O. Skubel

CERTIFICATE OF SERVICE

This is to certify that on January 7, 2002, I caused a copy of the Supplement to Complaint Counsel's Motion to Compel Compliance With Subpoenas *Ad Testificandum* and *Duces Tecum* to be served by hand upon the following persons:

The Honorable D. Michael Chappell
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Marimichael O. Skubel, Esquire
KIRKLAND & ELLIS
655 Fifteenth Street, N.W.
Washington, D.C. 20005
(202) 879-5034
Fax (202) 879-5200

Counsel for MSC.Software Corporation

J. Dennis Harcketts

J. Dennis Harcketts
Bureau of Competition
Federal Trade Commission
Washington, D.C. 20580
(202) 326-2783
Facsimile (202) 326-3496

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

RESPONDENT SCHERING-PLOUGH CORPORATION'S RESPONSE TO COMPLAINT COUNSEL'S MOTION FOR EXTENSION TO RESPOND TO MOTIONS IN LIMINE

Respondent Schering-Plough Corporation ("Schering") respectfully submits this memorandum in response to complaint counsel's motion to extend its time to respond to respondents' motions in limine until January 14, 2002.

1. The Third Revised Scheduling Order provides that responses to motions in limine are due on January 10, 2002.

2. On January 3, complaint counsel asked if respondents would agree to support a four-day extension of the time to respond to motions *in limine*, so that responses will be due on January 14.

3. Ordinarily, Schering would consent to a four-day extension such as that requested by complaint counsel. The parties have worked together to accommodate similar requests for brief extensions throughout this proceeding whenever possible. However, Schering is very concerned that an extension for complaint counsel's responses

to all of respondents' motions *in limine* would unduly shorten the period in which the Court may consider the motions, given the proximity of the final prehearing conference and the hearing itself.

4. The majority of respondents' motions *in limine* relate to evidence that complaint counsel intends to present in its case in chief. For example, two of respondents' motions seek to exclude or limit the testimony of complaint counsel's expert witnesses Dr. Nelson L. Levy and Dr. Timothy Bresnahan. Another of respondents' motions seeks to limit complaint counsel's use of investigative hearing and deposition testimony at the hearing. The resolution of these motions will affect the evidence that the present will present at the hearing. Schering respectfully submits that the Court will at least be inconvenienced, and may not have sufficient time to consider these motions *in limine* before the hearing, if complaint counsels' responses are not filed by January 10.

5. The motions *in limine* relating to complaint counsel's rebuttal experts, Drs. Pitt, Bazerman, Banakar and Adelman could conceivably be resolved after the hearing has begun. Thus, Schering agrees with respondent Upsher-Smith's suggestion that complaint counsel's time to respond to those three motions *in limine* could be extended until January 14, 2002, without prejudice to the parties or undue inconvenience to the Court.

CERTIFICATE OF SERVICE

I hereby certify that this 7th day of January 2002, I caused an original, one paper copy and an electronic copy of Respondent Schering-Plough Corporation's Response to Complaint Counsel's Motion for Extension to Respond To Motions in Limine to be filed with the Secretary of the 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 one paper copy was hand delivered upon:

David Pender
Assistant Director, Bureau of Competition
Federal Trade Commission
Room S-3115
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Karen Bokat
Federal Trade Commission
Room 3410
601 Pennsylvania Ave, N.W.
Washington, D.C. 20580

Christopher Curran
White & Case LLP
601 13th St., N.W.
Washington, D.C. 20005

Diane E. Bieri

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

RESPONDENTS' JOINT MOTION TO EXCLUDE THE EXPERT TESTIMONY OF DR. NELSON L. LEVY

Respondents Schering-Plough Corporation ("Schering") and Upsher-Smith Laboratories, Inc. ("Upsher-Smith") respectfully submit this motion to exclude the expert testimony of Nelson L. Levy. Complaint counsel offers Dr. Levy as a proposed expert witness in support of complaint counsel's allegation that the license payments from Schering to Upsher-Smith for Niacor-SR and other pharmaceutical products were in fact disguised payments to keep Upsher-Smith from entering the market with a generic version of Schering's K-Dur.

Dr. Levy's experience does not qualify him to give the testimony complaint counsel has requested, however. Dr. Levy is not a cardiologist and is plainly not knowledgeable about cholesterol-reducing drugs. He has little or no experience in marketing and no experience in the valuation of pharmaceutical products. He has meager experience in in-licensing pharmaceutical products at large companies (since 1983 he has worked at only one for fourteen months in the early 1990s), he has no regulatory expertise, and no experience in marketing drugs overseas. Moreover, his conclusion

rests, in large part, on his determination that the fact witnesses in this case are lying. Dr. Levy may not opine on the credibility of witnesses or Schering's intent, however, and his opinion in this regard must be excluded.

For these reasons, as set forth in the accompanying joint memorandum, Respondents respectfully request that the Court grant this motion, and exclude the testimony of Dr. Levy.

Respectfully submitted,

Laura S. Shores

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

Attorneys for Respondent
Schering-Plough Corporation

WHITE & CASE LLP

By: _____
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J. Mark Gidley
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601 Thirteenth Street, N.W.
Washington, D.C. 20005-3807
Telephone: (202) 626-3600
Facsimile: (202) 639-9355

Attorneys for Respondent
Upsher-Smith Laboratories, Inc.

Dated: January 3, 2002

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

MEMORANDUM IN SUPPORT OF RESPONDENTS' MOTION TO EXCLUDE THE EXPERT TESTIMONY OF DR. NELSON L. LEVY

Respondents Schering-Plough Corporation ("Schering") and Upsher-Smith Laboratories ("Upsher-Smith") submit this memorandum in support of their motion to exclude the expert testimony of Nelson L. Levy.

I. INTRODUCTION

Complaint counsel contends that the $60 million (made in three payments over two years) Schering paid Upsher-Smith for the license rights to market Niacor-SR, a sustained-release niacin product to treat elevated cholesterol, and three other pharmaceutical products in Europe cannot reasonably be considered to have been a licensing fee. Complaint counsel contends that the payments were instead disguised payments to Upsher-Smith to refrain from entering the market with its generic version of Schering's K-Dur.

Complaint counsel has no direct evidence to support this claim. The Niacor-SR product was evaluated in writing by a uniquely well-credentialed official at Schering—an

official who knew nothing about the patent case or its settlement. And every witness who knew about the license has testified that it was a *bona fide* transaction. Schering will call these witnesses live at trial.

Complaint counsel plans to prove its contention through the opinion testimony of an expert witness, Dr. Nelson Levy. Dr. Levy will testify that in his opinion, and contrary to the testimony of every fact witness in the case, that: [

].

As set forth more fully below, Dr. Levy's experience does not qualify him to give expert testimony on these subjects. Dr. Levy is medically trained and spent three years in the Research and Development department of Abbott Laboratories—a large pharmaceutical manufacturer—in the early 1980s. However, Dr. Levy is not a cardiologist and is plainly not knowledgeable about cholesterol-reducing drugs. He has little or no experience in marketing, and virtually none in the valuation of pharmaceutical products. He has meager experience in in-licensing pharmaceutical products at large companies (in the seventeen years since 1983 he has worked at only one such company for fourteen months in the early 1990s), he has no regulatory expertise, and no experience in marketing drugs overseas.

Dr. Levy betrayed his lack of experience related to cholesterol-reducing drugs in his deposition. He testified that [

] FDA and all experts in the field, including complaint counsel's rebuttal expert, Dr. Pitt, agree that the relevant benchmark is 3 times ULN. As a result, Dr. Levy drew wild conclusions about [

]. Further, Dr. Levy thought that [

]. And he believed [

]. Biopsies involve inserting a large needle through the skin and flesh into the liver and extracting a plug of the liver itself. Not surprisingly, Dr. Levy's astonishing testimony on this subject drew no agreement from complaint counsel's other expert. *See* Pitt Dep. (attached as Exhibit 1 to Memorandum in Support of Respondents' Motion to Limit the Rebuttal Testimony of Dr. Bertram Pitt Regarding Conversations with FDA Officials) at 47-49.

Because Dr. Levy's clinical research experience does not include any experience with cholesterol-reducing drugs or with the FDA approval process, he has nothing to offer in the way of expertise on the prospects for FDA approval. And because he has no experience in marketing or in-licensing drugs for sale outside North America, he is uniquely ill-suited to second-guess Schering's sales projections and Schering's valuation of the rights to Niacor-SR. Finally, his four years of work at pharmaceutical companies, most of which occurred almost twenty years ago, does not begin to qualify him to testify to what due diligence "standards" exist in the industry today.

Finally, Dr. Levy's opinion that [

] is squarely at odds with the sworn testimony of the witnesses involved in the transaction. His opinion thus rests heavily on his conclusion that these witnesses, none of whom he has ever laid eyes on, are not telling the truth. (Deposition of Nelson Levy ("Levy Dep." at) (attached as Exhibit 1 hereto) ([

]). And, believing that his experience qualifies him to opine on Schering's motivations, he also intends to opine that [

]. *See* Levy Dep. at [ ] ([

]). Under dispositive case law, an expert witness may not opine on the credibility of fact witnesses or on a party's intent, and Dr. Levy's opinions in this regard are inadmissible.

II. DISCUSSION

A. Principles Governing the Qualifications of Experts

1. The Expert's Area of Expertise Must Match the Subject Matter of His Testimony

Courts have "broad discretion" to exclude expert testimony. *In re Natural Organics, Inc.*, 2001 FTC Lexis 25 *9 (Feb. 26, 2001). A purported expert witness must have expertise on each of the particular matters upon which he intends to render an opinion:

> Even where a witness has special knowledge or experience, ***qualification to testify as an expert also requires that the area of the witness's competence matches the subject matter of the witness's testimony.*** Thus, the courts have frequently precluded a witness from testifying as an expert where the witness has specialized knowledge on one subject but offers to testify on a different subject.

29 C. Wright & V. Gold, *Federal Practice & Procedure*, § 6265 at 255-56 (1997) (emphasis added). *See also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999) ("The trial court had to decide whether this particular expert had sufficient specialized knowledge to assist the jurors 'in deciding the particular issues in the case.'"). When an expert lacks the requisite credentials, it is not simply a matter of according less weight to his testimony—the proper remedy is to exclude the testimony. *See In re Air Crash Disaster at New Orleans*, 795 F.2d 1230, 1233 (5th Cir. 1986) ("[W]e recognize the temptation to answer objections to receipt of expert testimony with the shorthand remark

that the jury will 'give it the weight it deserves.'. . . . [but] [t]rial judges must be sensitive to the qualifications of persons claiming to be experts.").

The law is also clear that the testimony of an expert who is not experienced in the specific field at issue, but is instead experienced in a more generalized field, or in a related one, should be excluded for lack of the requisite qualifications. *See Coal Resources, Inc. v. Gulf & Western Indus., Inc.*, 954 F.2d 1263, 1268 (6th Cir. 1992) (CEO of coal company with expertise on development of mining rights not qualified as expert on costs and appropriateness of coal preparation plants); *United States v. Chang*, 207 F.3d 1169, 1173 (9th Cir. 2000) (expert in international finance cannot opine whether international securities were counterfeit); *McDonald v. Federal Labs, Inc.*, 724 F.2d 243, 248 (1st Cir. 1984) (expert on chemistry of mace cannot opine on mace canister design); *Wilson v. Woods*, 163 F.3d 935, 937 (5th Cir. 1999) (expert with 25 years' experience consulting on fire reconstruction and teaching mechanical and industrial engineering cannot opine on auto accident reconstruction where he never taught, conducted studies or published in that field); *Barrett v. Atlantic Richfield Co.*, 95 F.3d 375, 382 (5th Cir. 1996)(expert on animal studies not qualified to testify on correlation between animal results and human results).[1] Courts particularly adhere to this rule to exclude medical experts where they attempt to provide an expert opinion beyond their particular fields of medicine in which they possess expertise. *See Edmonds v. Illinois Central Gulf R. Co.*,

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[1] *See also United States v. Kladouris*, 964 F.2d 658, 669 (7th Cir. 1992) (witness with general knowledge of hydrocarbons not qualified as an expert on chemistry of fire causation); *Firemen's Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1180 (3d Cir. 1976) (geologist not an expert on seismology); *Jones v. Lincoln Elec. Co.*, 188 F.3d 709, 724 (7th Cir. 1999) (abuse of discretion not to exclude metallurgist from testifying on health effects of manganese); *City of Hobbs v. Hartford Fire Ins. Co.*, 162 F.3d 576, 587 (10th Cir. 1998) (expert with 30 years experience in handling and adjusting third-party claims not qualified to opine on first-party claims); *McCullock v. H.B. Fuller Co.*, 981 F.2d 656, 657 (2d Cir. 1992)(electrical and industrial engineer not qualified to opine on adequacy of warning label).

910 F.2d 1284, 1287 (5th Cir. 1990) (clinical psychologist not qualified as expert on whether stress worsened coronary disease).[2]

This rule has also been specifically applied to experts who wish to opine on issues of valuation. Courts regularly exclude purported experts who have merely demonstrated some general experience or expertise, but who lack the specific expertise necessary to perform the valuation of the asset in question. *See Suitum v. Tahoe Regional Planning Agency*, 80 F.3d 359, 363 (9th Cir. 1996) (vacated on other grounds) (excluding expert on development rights transfers as not qualified to opine on market valuation of development rights.

Further, it is well established that where geographic distinctions matter, even a witness with great experience in one geographic area is not qualified to render expert opinions on other regions. *See Taylor v. Ouachita Parish School Bd.*, 648 F.2d 959, 970 (5th Cir. 1981) (affirming exclusion of "able sociologist with a fine academic record" who had studied segregation in 16 cities but not the city at issue).[3] Thus, an expert on the value of real estate in California would not be qualified to opine on the value of a piece of real estate in Massachusetts.

Finally, supervision of others while in an executive position at a company does not itself qualify a person as an expert on the matter supervised. *See Coal Resources, Inc.* 954 F.2d at 1268 (rejecting plaintiff's assertion that CEO's approval and review of all coal preparation plant construction and modification during his tenure qualified him as expert on the costs and appropriateness of such plans; holding "review of plans and

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[2] *See also Watkins v. Schriver*, 52 F.3d 769, 771 (8th Cir. 1995) (neurologist not qualified to opine on accident reconstruction in case involving paralyzing neck injury); *Gates v. United States*, 707 F.2d 1141, 1145 (10th Cir. 1983) (professor of immunology not qualified to review particular patient's medical records).

[3] *See also United States v. Hirschberg*, 988 F.2d 1509, 1514 (7th Cir. 1993) ("knowledge of police practices in Chicago does not qualify Illinois police detective as expert on practices in Miami"); *Koch v. Gorilla*, 552 F.2d 1170, 1173 (6th Cir. 1977) (expert on medical standards in Duluth cannot testify on standards in community located 100 miles away).

budgets prepared by others differ substantially from the preparation and design of the plans" himself).

2. An Expert May Not Testify on the Credibility or Motivation of Witnesses

It is fundamental that assessments of credibility belong to the trier of fact, and are not a proper subject for expert testimony. *See Wright & Gold*, § 6262 at 178 (Rule 702 "seeks to preserve the trier of fact's traditional powers to decide the meaning of evidence and the credibility of witnesses"). *See, e.g., United States v. Awkard*, 597 F.2d 667, 671 (9th Cir. 1979) (error to allow expert to testify on witness' ability to recall incident: "opinion testimony on credibility is limited to character; all other opinions on credibility are for the jurors themselves to form"); *United States v. Benson*, 941 F.2d 598, 604 (7th Cir. 1991) ("credibility is not a proper subject for expert testimony").

It is equally improper for an expert to testify about a party's intent or motivation. *See, e.g., Aerotech Resources, Inc. v. Dodson Aviation, Inc.*, 2001 U.S. Dist. LEXIS 5646, *6-*7 (D. Kan. Apr. 4, 2001) (improper for expert to testify about intended effect of agreement, as that was province of factfinder); *In re Diet Drugs Products Liability Litigation*, 2001 U.S. Dist. LEXIS 1174, *7 (E.D. Pa. 2001) ("any proffered expert testimony concerning the intent of AHP or any other entity (such as the FDA) shall be excluded on the basis that the question of intent is to be determined by the jury, not experts").

B. Dr. Levy is Not Qualified to Render an Opinion on Whether the Rights to Market Niacor-SR Outside North America Were Worth $60 Million

1. Factual Background

a. The licensed product. Niacor-SR, a sustained release niacin formulation being developed by Upsher-Smith was the principal product involved in the licensing transaction at issue. Niacin (vitamin B-3) is a well-known compound, which

Dr. Levy admits [ ]. (Report of Nelson Levy ("Levy Rep."), attached hereto as Exhibit 2, at [ ]). Well before 1997, niacin was recognized (as it is now) as a good complement to statins (such as Mevacor and now Lipitor) for use in combination therapy in the management of cholesterol and lipid levels. However, as of 1997, the use of niacin was limited because the then-available immediate-release niacin products frequently produced unpleasant side effects. Niacor-SR, however, utilized a novel sustained-release technology, which, by introducing niacin into a patient's system more gradually, offered the promise of fewer side effects. Because Upsher-Smith planned to market Niacor-SR in North America on its own, Schering and Upsher-Smith negotiated a license giving Schering the rights to market Niacor-SR outside North America. Thus, the principal targets for Schering were Europe and Asia's multi-billion dollar markets for cholesterol-lowering drugs.

Shortly before negotiating with Upsher-Smith for the rights to market Niacor-SR outside North America, Schering had negotiated with a company called Kos Pharmaceuticals, Inc. ("Kos"), for the rights to co-market its sustained-release niacin product, known as Niaspan. Schering did detailed sales projections for Niaspan in the United States, and concluded that its sales would exceed $100 million per year and that the profits had a net present value of over $250 million. Market analysts predicted even greater sales for Niaspan of over $250 million per year, and Kos (then a one-product company) raised $60 million from the public in an initial public offering in exchange for less than 30 percent of Kos' stock. Partly because of the fact that Kos' expectations for Niaspan exceeded Schering's, no transaction with Kos was ever consummated.

When the opportunity arose to acquire the rights to market Niacor-SR outside North America in June 1997, Schering once again prepared sales and profit projections. The Schering official who performed these projections, James Audibert, was uniquely qualified to do so. He is scientifically trained and had spent several years in Research and Development inside a pharmaceutical company. He was extraordinarily

knowledgeable about cholesterol-reducing drugs, having made them a special focus of his study and work during the previous six months. He had extensive experience in sustained-release technology and in bringing sustained-release formulations of old drugs to market. He was in 1997 a member of Schering's Global Marketing division, and had experience in markets outside the United States.

Mr. Audibert reviewed the results of the Niacor-SR clinical trials provided by Upsher-Smith. He projected annual sales for Niacor-SR of over $100 million after its third year on the market—sales which would yield a profit to Schering with a net present value of $225-265 million.

b. **Dr. Levy's opinion.** Dr. Levy does not question that in 1997 Schering had the experience and acumen to evaluate and market a drug such as Niacor-SR on a successful basis. But he nonetheless renders the opinions that [

]. Based on these opinions Dr. Levy cavalierly concludes that the payments for the license reflect [

]. (*Id.*).

c. **Dr. Levy's Credentials.** After completing his medical education in the 1967 and obtaining a Ph.D. in immunology 1973, Dr. Levy spent eight years at Duke University doing academic research and teaching on cancer immunology, neurology, multiple sclerosis and brain control of the immune system. ( ). He does not report having done any research in the field of cardiology. He is board certified in allergy and immunology. He is not board certified in cardiology.

Starting in 1981, he spent three years at a pharmaceutical company, Abbott Laboratories, overseeing drug research on HIV, infections, hypertension and prostatic hypertrophy. (*Id.*). During the course of his deposition he could not identify any

instance in which he oversaw or did any research on any niacin products, any of the statins, or any other cholesterol reducing agent. *See generally* Levy Dep.

For nearly all of the 17 years since he left Abbott, Dr. Levy has worked out of his home, running a small consulting firm with two other professionals advising start-up companies and investors, quite unlike Schering, principally on product development. (*Id.*; Levy Dep. 99). In response to questions regarding his qualifications and experience, the one product that he proffered as an example of a product that CoreTechs, his consulting operation, was working on was a [

]. (Levy Dep. [ ]).

Finally, more than seven years ago Dr. Levy briefly headed the U.S. operations of a Japanese pharmaceutical company, Fujisawa, with no claim that any of the drugs with which he dealt treated cholesterol or were similar to Niacor-SR in terms of pharmacology or market prospects. (Levy Rpt. 1). [

]. Levy has not been employed by a pharmaceutical company in any capacity since 1993. (*Id.* at [ ]).

Unlike Mr. Audibert, Dr. Levy has no expertise in cholesterol-reducing drugs, no expertise in sustained-release technology, no marketing or valuation experience, and absolutely no experience marketing or licensing drugs outside North America. Given his credentials, it is surprising that Dr. Levy believes he is qualified to second-guess Mr. Audibert's evaluation of Niacor-SR, and astonishing that he purports to render an opinion that [

].

2. Dr. Levy Is Not An Expert On Valuing A License For The Sale Of Pharmaceuticals Anywhere – Let Alone In European Market

a. Dr. Levy is Not Qualified to Value the Niacor-SR License

Dr. Levy has no experience, education or training that qualifies him to appraise the value of the Niacor-SR license. First, Dr. Levy's educational and teaching background through 1981 does not qualify him to evaluate the value of a pharmaceutical products license. He never attended business school, he has not written any articles on the topic of valuation of pharmaceutical licenses, and he never took or taught any courses on the subject. Moreover, Dr. Levy himself admits that when he left academia:

(Levy Dep. [ ]). Thus, any claim to expertise necessarily depends on his subsequent work experience. And little or none of it involves marketing or valuation of pharmaceuticals.

Dr. Levy's brief tenure at two pharmaceutical corporations many years ago, where he supervised research in therapeutic areas unrelated to cardiology and cholesterol and presided briefly over the American subsidiary of a Japanese company, does not provide him with the relevant expertise. His experience overseeing R&D at Abbott is inapposite – experience in scientific research does not make one an expert in other aspects of the business, such as valuation and marketing. *See, e.g., Chang,* 207 F.3d at 1173 (international finance expert cannot opine on whether international securities were counterfeit). Likewise, Dr. Levy's ill-starred 14 months at Fujisawa, where he merely supervised others, does not qualify him as an expert. *See, e.g., Coal Resources,* 954 F.2d at 1268 (CEO's oversight of coal plant construction did not qualify him as an expert on construction budgets and plans prepared by others).

Dr. Levy's own description of his work history confirms that he is unqualified to opine regarding pharmaceutical license valuations generally:

- He admits that [

].

- He admits that [

  ].

- He admits that [

  ].

- He admits that [

  ].

- His CV indicates that he has in-licensed only two major drugs in his lifetime (*id.* 81) and, although in his deposition he claimed [
  ], he admits [
  ].

For these reasons alone his opinions on the valuation of Niacor-SR do not meet the requirements of *Daubert* and *Kumho* and Rule 3.43(b).

b. Dr. Levy Lacks Experience in Cholesterol-Reducing Drugs

Dr. Levy, as he admits, is not an expert on lipidology and cholesterol, which is at the very heart of Niacor-SR's technology:

Q: [

]

A: [

]

(Levy Dep. [ ] (emphasis added)). He could not [

].

The only knowledge Dr. Levy may possess regarding cholesterol is based on [

]. (*Id.*). This knowledge is plainly outdated and an insufficient a basis for an expert opinion on new drugs or the current regulatory environment and market conditions. *See Posado v. Deters*, 5 F.3d 119, 124 (5th Cir. 1993) (excluding expert who had not worked in relevant field in almost 20 years and had not taken any refresher courses). For example, during the course of his deposition he [

].[4] Obviously, a new drug's prospects for FDA approval depend on the current state of the art. (*Id.*). Dr. Levy's research after medical school [

]. (*Id.* [ ]). He also has no professional experience with [

]. (*Id.* [ ]).

c. Dr. Levy is Not Qualified to Opine on European Market Potential

Dr. Levy also has no expertise in marketing or licensing drugs outside North America. The prospects for drugs differ among various geographical markets due to differences in drug pricing, regulatory structures, prescribing patterns, and insurance coverage, among others factors. Dr. Levy [ ].[5]

---

[4] [

].

[5] Indeed, one of Dr. Levy's criticisms is that [

]. (Levy Rep. at [ ]).

This is striking because not only is Dr. Levy's general experience with valuing pharmaceutical drugs marginal at best, but by his own admission he has [

]. In his deposition he admitted that:

- [
-
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-
-
-

]

In fact, it is apparent from these admissions that Dr. Levy's knowledge regarding niacin in Europe and European markets and licensing generally is based on what he has learned from reading depositions in this case. Knowledge gained through work as a witness, however, does not count toward an expert's credentials. 29 *Wright & Gold*, § 6265 at 248. Indeed, courts routinely exclude expert testimony where the expert is merely interpreting the deposition testimony of the witnesses. For example, one court excluded an expert who relied "almost exclusively on his interpretation of deposition testimony" to reach his conclusions because in so doing the witness "does not serve as an expert, but seeks to supplant the role of counsel in making argument at the trial and the

role of the jury interpreting the evidence." *Primavera Familienstifung v. Askin*, 130 F.Supp. 2d 450, 528 (S.D.N.Y. 2001).

In sum, Dr. Levy simply lacks the expertise to evaluate cholesterol-reducing drugs or to value any drug for marketing either here or in Europe. He plainly lacks expertise to opine, as he does, that Schering personnel must have been [ ] (Levy Dep. [ ]) to value Niacor-SR's European potential as they did. Without knowing the range of reasonable values for a license for Niacor-SR in Europe, Dr. Levy's conclusions regarding the license agreement are unsupportable.

3. Dr. Levy Is Not Qualified To Render an Opinion Regarding the Likelihood of FDA or European Regulatory Approval For Niacor-SR

Dr. Levy is similarly unqualified to opine regarding the likelihood of regulatory approval of Niacor-SR in 1997. His lack of expertise is demonstrated not only by his lack of qualifications regarding U.S. approval of cholesterol-fighting drugs, but also by the jarring fundamental errors in his description of Niacor-SR and the applicable FDA standards. Further, in his deposition he effectively admitted he was [ ]. Accordingly, his opinion that Schering should have concluded that the side effects of Niacor-SR raised questions regarding FDA or European approval is neither correct nor admissible.

At no point in his brief corporate pharmaceutical career did Dr. Levy ever have substantial involvement with issues related to regulatory approval. His three years as a laboratory researcher [ ]. Levy Dep. at [ ]. And his consulting work out of his home over the past 17 years has not [ ]. *See id.* at [ ]. Dr. Levy never worked for the FDA or a regulatory agency in any European country, and does not claim [

]. *Id.* at [ ].

Dr. Levy revealed his ignorance of European regulatory approval procedures during his deposition. He was unable [

] Plainly, Dr. Levy is not qualified to opine on the likelihood and timing of approval of Niacor-SR by European regulators.

Moreover, Dr. Levy's opinion regarding the likelihood of regulatory approval of Niacor-SR depended on his views on the drug's potential liver toxicity. That opinion rests primarily on data received by Schering showing that [

]. According to Dr. Levy, [

].

Not only does Dr. Levy lack any professional basis to opine that [

], the evidence is clear that he could not be more wrong. Liver enzyme levels of 1.5 times ULN cause no concern at FDA at all. Indeed, the subjects in cholesterol drug clinical trials, such as those conducted by Upsher-Smith on Niacor-SR, can and do *begin* the trials with liver enzyme levels of up to 1.5 times ULN. FDA told Upsher-Smith the relevant standard was 3 times ULN and this is the standard the FDA used in evaluating all the other major cholesterol reducing agents

(including the blockbuster statins).[6] *See* [

).

Moreover, other experts in this case who opine on this issue, including Complaint Counsel's rebuttal witness Dr. Pitt, confirm that the relevant standard is 3 times ULN. *See, e.g.*, Pitt Rep. 5; Horowitz Rep. 14-15; McVey Rep. 11. In light of this record and the total absence of evidence that "other experts in the industry" (or the FDA) uses Dr. Levy's [ ], his opinion regarding the FDA approval (and therefore the reasonableness of the license agreement) should be excluded. *Kumho*, 526 U.S. at 157.

Indeed, Dr. Levy made several other strikingly erroneous assertions regarding FDA approval. Based on his incorrect assumption that [

]. These speculations on his part are again at odds with standard practice and the opinions of the other medical experts in this matter, including Dr. Pitt. (Pitt Dep. at 12). Moreover, through questioning it became clear that his basis for these conclusions was not any experience with the FDA, but that [

]. Finally, Dr. Levy even asserted that [

]. In fact, however, such tests are not required for known compounds (such as niacin) and no such studies had been conducted. Thus, the basis for his conclusions is not properly tethered to reality and, as the Supreme Court cautioned, "nothing...requires a district court to admit

[6] Cholesterol drugs which cause liver enzyme levels to exceed 3 times ULN in some percentage of patients may nonetheless be approved. Davidson Dep. at 89-92. FDA recommends liver enzyme monitoring for such drugs. Horovitz Dep. at 190-93.

[7] It does not appear that Dr. Levy has been a general practitioner for at least two decades.

evidence that is connected to existing data only by the *ipse dixit* of the expert." *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997).

For these reasons, Dr. Levy's conclusions regarding the approvability of Niacor-SR are fatally flawed, and thus his conclusions regarding the reasonableness of the license agreement is without foundation and should be excluded.

C. Dr. Levy Failed to Use Reliable Methods and Principles in Reaching His Conclusion as to Valuation of Niacor-SR and the Other Licensed Products

Even if Dr. Levy's credentials were sufficient to qualify him on the valuation of pharmaceutical licenses, his methods and conclusions fail to meet the standard of reliability *Daubert, Kumho,* and Rule 3.43(b) require. Indeed, although Dr. Levy purports to opine on the reasonableness of the license agreement negotiated by Schering and Upsher-Smith, he rejects [

]. Having done this, however, he fails to perform any quantitative valuation of Niacor-SR, let alone the other pharmaceutical products Schering licensed.

As part of its internal process for approving the Niacor-SR license, Schering performed a detailed financial analysis of the value of the drug to Schering. As part of that analysis, Mr. Audibert concluded in a June 17, 1997 memorandum that Niacor-SR would produce profits fo $345 million in its first five years of sales. (SP 1600035-36). Mr. Audibert's documents have been produced, and he has stood by his valuation throughout both of his depositions.

Dr. Levy nonetheless opines that the license fees [

] Levy Dep. at [ ]. Yet nowhere in his report, or, for that matter, anywhere else, does Dr. Levy provide a calculation of what he believes the Niacor-SR license was worth.

The use of net present values (NPVs) to determine the value of a license is a long-established practice in the pharmaceutical industr. See Deposition of James Egan (former Searle executive) at 12 -13 (describing use of discounted cash flow model to determine whether NPV of product made it a good candidate for in-licensing). Indeed, every economic expert in the case agrees on this point.

Dr. Levy's explanation [ ],

however, is contrary to the accepted practice in the pharmaceutical industry: [

]

Levy Dep. at [ ]. Although acknowledging [

].

Tellingly, Dr. Levy also concedes [

] *Id.*

Where an expert's opinion deviates from the majority view, he is obligated to show that the alternative method he suggests is employed by at least a recognized minority of within the field. *See Daubert v. Merell Dow Pharms., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) (scientific experts might be permitted to testify if they could show that the methods they used were also employed by "(at least) a recognized minority of scientists in their field."). Moreover, where an expert claims to be applying principles and methods in accordance with standards in the field, but reaches a conclusion that other valuation experts would not reach (here, that [ ]), the trial court should be skeptical. Fed. R. Evid. 702, Committee Note (2000 Amendment) ("[W]hen an expert purports to apply principles and methods in accordance with professional standards, and

yet reaches a conclusion that other experts in the field would not reach, the trial court may fairly suspect that the principles and methods have not been faithfully applied.") (citing *Lust v. Merrell Dow Pharms., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996).

Dr. Levy's report cannot meet this requirement of Rule 702. He simply does not propose his own method of evaluating the value of the license agreement, let alone provide a quantitative valuation of the license agreement. Instead, his opinion is exactly that – his ***personal*** opinion. Even a cursory review of his report reveals that his is not relying on any objective or industry standard, but rather his own gut feelings:

- [
-
-
-
-
-
]

These statements in his report articulating a personal rather than industry standard, combined with Dr. Levy's resort in his deposition to unsupported and often inflammatory rhetoric, rather than reasoned analysis,[8] only further demonstrates his unfamiliarity with the standards prevailing in the industry at the time the licensing agreement Schering and Upsher-Smith in June 1997.

[8] During his deposition, in the guise of analysis, Levy offered a variety of epithets and pejorative conclusions about the license agreement and the work of the pharmaceutical employees of Schering-Plough. *See* Levy Dep. [

]

Dr. Levy's reliance on inexact conclusory statements, which are based on his personal reactions, and his failure to perform the analysis that is standard in the industry is simply another reason Dr. Levy's opinion should be excluded. *See Navarro v. Fuji Heavy Indus., Ltd.*, 925 F. Supp. 1323, 1329 (N.D Ill. 1996) (finding an expert witness's affidavit inadmissible as it "includes nothing defining the 'reasonable standard of care' in the industry, much less any information showing that Fuji failed to conform to such a standard."). As he does not offer an alternative industry standard for valuation, Dr. Levy's testimony "supplies nothing but a bottom line [and] supplies nothing of value to the judicial process . . . ." *Id.* at 1329 (internal citations and quotations omitted). Because Dr. Levy's opinion is not based on any reliable principles or methods but rather unsupported and conclusory opinions which do not assist the Court, his expert report should be excluded.

D. Dr. Levy Is Not Qualified To Render An Opinion On The Credibility Of Schering Witnesses Or Schering's Intentions In Entering Into The License Agreement

Dr. Levy concludes that Schering witnesses, [

]

Expert opinion does not assist the trier of fact "if it draws inferences or reaches conclusions within the jury's competence or within an exclusive function of the jury." *Nichols v. American National Insurance co.*, 154 F.3d 875, 883 (8th Cir. 1998). In *Nichols*, a psychiatric expert testified as to the "psychological credibility" of the plaintiff

in a sexual harassment case. The expert testified that "recall bias, secondary gain and malingering" influenced the plaintiff's testimony. *Id.* The Court held that the expert "used these terms to indicate that [the plaintiff's] version of the facts was inconsistent and changed over time and that it was tainted by bias and desire for financial gain." *Id.* at 884. Because these were "inferences" that the jury was required to draw, the Court excluded the expert's opinion on the grounds that it "impermissibly instructed the jury on how to weigh . . . evidence." *Id.*

Similarly, in *Securities and Exchange Commission v. Lipson*, an accounting expert offered an opinion that the defendant would not have traded stocks on the basis of his company's internal reports because the defendant believed that those reports were unreliable. The court refused to admit this testimony because "all of [the expert's] years of training and experience as an accountant . . . do not specially equip him to divine what Defendant truly believed about the reliability of the reports." 46 F. Supp. 2d at 763. The court characterized the experts' opinions as "at worst, rank speculation" and "at best, . . . credibility choices that are within the province of the jury, not [the expert], to make." *Id.* *Cf. In re Diet Drugs,* 2000 U.S. Dist. LEXIS 9037, * 22 ("testimony of an expert that constitutes mere personal belief as to the weight of the evidence invades the province of the jury"); *DeJager Construction, Inc. v. Larry Schleninger*, 938 F.Supp. 446, 449 (W.D. Mich. 1996) (expert's opinion excluded where expert selected portions of record supporting client's position and then opined on credibility of witness statements).

Nothing in Dr. Levy's background qualifies him to give "expert" testimony to the effect that Schering witnesses lied in their depositions. To the extent his opinion is based on his belief that Schering's due diligence fell below some "standard" in the pharmaceutical industry, it is inadmissible: Dr. Levy has been out of the industry for far too long to render an expert opinion on this subject.

To the extent Dr. Levy's opinion is based on his belief about their credibility, he must not be permitted to render it at the hearing. The question whether Schering

witnesses are telling the truth is one for this Court to decide for itself. Dr. Levy is equally unqualified to opine on Schering's motivations in entering into the license agreement. In his deposition, he testified that, [

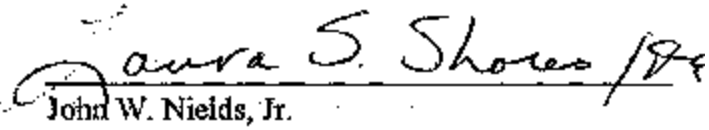
]

Dr. Levy's beliefs about Schering's motivations must be excluded. The intent or motivation of a party is a matter for the trier of fact, not experts. In *Aerotech*, for example, an aviation consulting expert proposed to testify that the parties' contract negotiations demonstrated an intent to establish an exclusive brokerage agreement rather than the sale of an aircraft. The district court excluded this testimony, on the ground that it "would speak to the effect that the parties intended their agreement to have. This is a task more properly performed by a fact finder." *Id.*; *see also Salas*, 980 F.2d at 305 ("conclusory assertions regarding [a defendant's] state of mind would not be helpful to a jury, [and are] not admissible."). Dr, Levy should be similarly precluded from testifying about the intentions of Schering and Upsher-Smith and entering the license agreement.

III. CONCLUSION

Because Dr. Levy has no specialized knowledge that will assist the Court in understanding the evidence or determining the disputed factual issues, his testimony should be excluded.

Respectfully submitted,



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Dated: January 3, 2002

Exhibit Redacted

Subject to Confidential Protective Order

Exhibit Redacted

Subject to Confidential Protective Order

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

ORDER GRANTING RESPONDENTS' JOINT MOTION TO EXCLUDE THE TESTIMONY OF DR. NELSON L. LEVY

The Court finds that the background and experience of complaint counsel's proposed expert, Dr. Nelson L. Levy, do not qualify him to offer his proposed testimony in this matter.

Accordingly, IT IS HEREBY ORDERED that Respondents' joint motion to exclude the testimony of Dr. Levy is hereby GRANTED, and Dr. Levy shall not be permitted to testify in this matter.

D. Michael Chappell
Administrative Law Judge

Dated: January _____, 2002

UNITED STATES OF AMERICA
BEFORE 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.

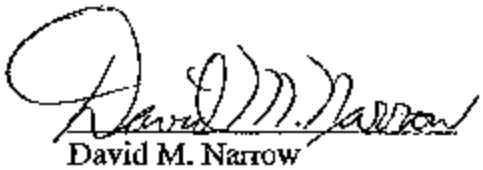
Docket No. 9297

PUBLIC VERSION
Redacted to Eliminate References to Deposition Testimony Designated as Confidential by Upsher-Smith Laboratories, Inc.

COMPLAINT COUNSEL'S MOTION *IN LIMINE* TO EXCLUDE EXPERT TESTIMONY OF ROBERT W. POLLOCK

Complaint counsel moves for an order excluding expert testimony by Robert W. Pollock at trial or in his expert report concerning or relating to: 1) the Hatch-Waxman Act or any provision or aspect thereof, including particularly the Act's 180-day exclusivity provisions; 2) any competitive assessment of the agreement, or any aspect of that agreement, between Upsher-Smith Laboratories, Inc. ("Upsher") and Schering-Plough Corporation ("Schering") settling the patent infringement litigation between them concerning K-Dur; and 3) the issue of possible approval or disapproval by the FDA of Upsher-Smith's New Drug Application ("NDA") for Niacor-SR. The bases for this motion are set forth in the accompanying Memorandum in Support of Complaint Counsel's Motion to Exclude Expert Testimony of Robert W. Pollock.

Respectfully Submitted,



David M. Narrow
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Bureau of Competition
Federal Trade Commission
Washington, D.C. 20580

Dated: January 8, 2002

UNITED STATES OF AMERICA
BEFORE 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** Redacted to Eliminate References to Deposition Testimony Designated as Confidential by Upsher-Smith Laboratories, Inc.

MEMORANDUM IN SUPPORT OF COMPLAINT COUNSEL'S MOTION *IN LIMINE* TO EXCLUDE EXPERT TESTIMONY OF ROBERT W. POLLOCK

Respondent Upsher-Smith Laboratories, Inc. ("Upsher-Smith") has designated Robert W. Pollock as an expert witness to testify regarding "FDA/Hatch-Waxman." Complaint Counsel moves for an Order in Limine to exclude under § 3.43(b) of the Commission's Rules of Practice Mr. Pollock's testimony as unreliable. Mr. Pollock's opinions, as proffered in his expert report dated October 8, 2001, include opinions about matters for which he is not qualified as an expert "by knowledge, skill, experience, training, or education" under Rule 702 of the Federal Rules of Evidence. Mr. Pollock is a pharmacist with no legal or economic training, yet he offers "expert" opinions on issues involving legal questions, competition, and technically-based FDA drug approvals where he has no training and little or no relevant experience.

Moreover, Mr. Pollock and Upsher-Smith have utterly failed to discharge their responsibility to demonstrate that Mr. Pollock's opinions meet the standard for reliability of

expert testimony as embodied in Rule 702 and established by Supreme Court and other relevant case law, beginning with *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), that such testimony be "based upon sufficient facts or data," is "the product of reliable principles and methods," and that the expert "has applied the principles and methods reliably to the facts of the case." Consequently, Mr. Pollock's testimony will not, and cannot, "assist the trier of fact to understand the evidence or to determine a fact in issue," the purpose of allowing expert testimony under Rule 702. Such flawed testimony necessarily is unreliable and therefore must be excluded from this proceeding under § 3.43(b) of the Commission's Rules.

For example, despite [redacted] Mr. Pollock, in his expert report, proceeds to offer opinions about the status at various times of the Hatch-Waxman Act's 180-day exclusivity provision, including interpretations of the legal effect of court decisions addressing those exclusivity issues. Mr. Pollock's expert report also includes an opinion regarding one issue - an assessment of the competitive nature of the patent infringement litigation settlement agreement between Schering and Upsher-Smith - that is entirely outside the area of expertise that Upsher-Smith has designated for Mr. Pollock's expert testimony ("FDA/Hatch-Waxman"), and is an issue on which Mr. Pollock also is entirely unqualified by education, training, or experience to render a reliable expert opinion. Finally, Mr. Pollock offers an opinion concerning the FDA's review and possible approval of a New Drug Application ("NDA") for Upsher-Smith's Niacor-SR product, despite [redacted]

[redacted], and based on very limited and inadequate factual information relating to the Niacor-SR NDA.

Nor did Mr. Pollock in his expert report (copy attached), or [redacted], identify any reliable principles or methods in his area of expertise that he used in forming his various opinions and reaching his conclusions, and to which he applied sufficient facts in a reliable manner in order to reach his "expert" conclusions, as required by Rule 702 of the Federal Rules of Evidence. The result is that Mr. Pollock's "expert" opinions are simply personal, lay opinions, ungrounded in any accepted body of expert learning or experience, not based on any reliable expert analytical methodology, and based on inadequate facts to form reliable expert opinions. His opinions, therefore, are of no assistance to a trier of fact and, under Rule 702, are not proper for consideration by a trier of fact. Section 3.43(b) of the Commission's Rules states that such unreliable evidence must be excluded in Commission adjudicative proceedings.

I. The Applicable Legal Standard for Expert Testimony

Section 3.43(b) of the Commission's Rules requires that "[i]rrelevant, immaterial, and unreliable evidence shall be excluded." (emphasis added). Thus, exclusion of unreliable evidence is mandatory, not discretionary, under the Commission's Rules. The Commission's Rules are silent as to what constitutes "unreliable evidence," or "unreliable" expert witness evidence, and § 3.43(b) makes no distinction between expert and other evidence. In such

instances, while not bound to follow the Federal Rules of Evidence,[1] the Commission frequently looks to the Federal Rules for guidance and often applies those Rules in its adjudicative administrative proceedings, especially where the Commission's own Rules are silent on an issue.[2]

Rule 702 of the Federal Rules of Evidence, which is the result of the Supreme Court's decisions on the issue of proper and allowable expert witness testimony,[3] is entirely concerned with assuring that only reliable and helpful expert testimony is admitted into evidence before a trier of fact. The Rule lays out the requirements for permissible expert testimony in federal court

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[1] *See FTC v. Cement Institute*, 333 U.S. 683, 705-706 (1948); *In re American Home Products* Corp., 98 F.T.C. 136, 368 n. 9 (1981); In *re Herbert R. Gibson, Sr.*, FTC Dkt. No. 9016, 1978 FTC Lexis 324, ALJ Initial Decision at 14-15 (May 19, 1978); *In re Thompson Medical Co., Inc.*, 101 F.T.C. 385, 388 n. 7 (1983) (Interlocutory Order) (citing 56 Fed.Reg. 56,862, 56,863 (1978) (comment of Commission on adoption of its discovery rules noting advisory, but non-binding, nature of Federal Rules)).

[2] *See, e.g., In re Olin Corp.*, 113 F.T.C. 400 at 600-602 (Commission upheld ALJ's exclusion of expert witness testimony due, in part, to failure of underlying data relied upon by expert to meet the standard of Rule 703 of Federal Rules of Evidence that data relied upon by expert be of a type normally relied on by experts in that field); *In re American Home Products Corp.*, 98 F.T.C. 136, 368 n. 9 (1981) (Commission relied on exception to the hearsay rule in Rule 803(8) of the Federal Rules of Evidence as additional support for admission into evidence of reliable scientific reports prepared by FDA experts pursuant to FDA regulations); *In re Amrep Corp.*, 102 F.T.C. 1362, 1379 (1983) (ALJ ordered sequestration of all witnesses at trial, following Rule 615 of Federal Rules of Evidence). *See also In re Textron,* Inc., 1990 FTC Lexis 483 at n.2 (December 27, 1990) (ALJ Order Denying Offer of Depositions) ("[the Federal Rules of Evidence] are pertinent only in the absence of direction of a Commission Rule of Practice."); In *re Thompson Medical Co., Inc.*, 101 F.T.C. 385, 388 (1983) (Interlocutory Order) ("Thus, the Commission has concluded that the more liberal view of discovery of experts under the Federal Rules [of Civil Procedure] is the one that should apply in Commission adjudications.").

[3] The Advisory Committee Note to Rule 702 (2001 Edition) observes (at p. 408) that the current content of Rule 702 is a response to the Supreme Court's rulings in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), charging trial judges with the responsibility of acting as gatekeepers to exclude unreliable expert testimony regarding any area of expertise.

proceedings, based on the standards enunciated by the Supreme Court in *Daubert* and *Kumho*. Rule 702 provides general standards that courts must use to assess the reliability and helpfulness of proffered expert testimony. The Rule states that "if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue" a witness "qualified as an expert by knowledge, skill, experience, training, or education" may testify thereto in the form of an opinion or otherwise "if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case."

The Advisory Committee Notes regarding the 2000 Amendments to Rule 702 explain that "the admissibility of all expert testimony is governed by the principles of Rule 104(a). Under that Rule, the proponent of proffered expert testimony has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence." (Federal Rules of Evidence Rule 702 at 408 (2001 edition) citing *Bourjaily v. United States*, 483 U.S. 171 (1987)).

Rule 702 requires that an expert witness be qualified as an expert by "knowledge, skill, experience, training, or education." As is discussed in more detail below, Mr. Pollock lacks any specialized training or education in the areas where he offers "expert" opinions. He is not an attorney or an economist, and has no training or academic degree in any specialized field other than pharmacy and pharmacy administration, neither of which is relevant to the issues on which he proffers opinions. Upsher-Smith claims that Mr. Pollock's area of expertise is "FDA/Hatch-Waxman." However, he holds no degree and has had no formal education or training in or relating to this area of expertise, [redacted]

[redacted] the pivotal district court decision in *Mova Pharmaceutical Corp. v. Shalala*, 955 F.Supp. 128 (D.D.C. 1997), which enjoined the FDA from granting final approval to a subsequent ANDA filer -- in derogation of the first filer's 180-day exclusivity rights -- based on the first ANDA filer's failure to meet the non-statutory requirement adopted in regulations by the FDA that the first filer successfully defend (*i.e.*, win) in a patent infringement suit against it brought by the pioneer drug company. [redacted]

Despite Mr. Pollock's experience working for the FDA and in areas involving the FDA, his experience does not provide him with any expertise to offer the kinds of opinions he proffers in his expert report. Moreover, even where Mr. Pollock's experience arguably is relevant to some of the opinions he offers, this experience is an insufficient basis for those opinions in light of his failure to adequately and explicitly explain how his conclusions derive from that experience. As the Advisory Committee Notes to Rule 702 state:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it." *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the expert's qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough."). The more subjective and controversial the expert's inquiry, the more likely the testimony should be excluded as unreliable. *See O'Conner v. Commonwealth Edison Co.*, 13 F.3d 1090 (7th Cir. 1994) (expert testimony based on a completely subjective methodology held properly excluded). (Notes p. 411).

Nowhere in his expert report [redacted] has Mr. Pollock explained "how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." While his report is entirely silent on these issues, in his deposition [redacted]

In fact, Mr. Pollock fails entirely, in [redacted] his report and [redacted], to identify any accepted body of knowledge or learning and experience in the areas of expertise that he claims qualify him to render expert opinions. He therefore entirely fails to explain how his conclusions are grounded in such an accepted body of learning or experience in this field. As the Advisory Committee Notes to Rule 702 state (at p. 410):

> The trial judge in all cases of proffered expert testimony must find that it is properly grounded, well-reasoned, and not speculative before it can be admitted. The expert's testimony must be grounded in an accepted body of learning or experience in the expert's field, and the expert must explain how the conclusion is so grounded. *See, e.g.*, American College of Trial Lawyers, *Standards and Procedures for Determining the Admissibility of Expert Testimony after* Daubert, *157 F.R.D. 571, 579 (1994) ("[W]hether the testimony concerns economic principles, accounting standards, property valuation or other non-*

scientific subjects, it should be evaluated by reference to the 'knowledge and experience' of that particular field.").

Furthermore, while information relied upon by an expert in reaching his or her conclusions itself need not be admissible into evidence, under Rule 703 of the Federal Rules of Evidence, for the expert's opinion or inference to be admissible, facts or data upon which an expert witness bases an opinion or inference must be "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences on the subject." As will be seen below, Mr. Pollock's opinions regarding the competitiveness of the Schering/Upsher-Smith settlement agreement and regarding the likelihood of the FDA's approving the Niacor-SR new drug application rely on inadequate information that does not meet the Rule 703 standard, and therefore his opinions on these issues are unreliable and not properly admissible.

II Mr. Pollock is Not Qualified by Training or Experience to Render Expert Opinions Concerning the Hatch-Waxman Act, any of its Provisions, or the Legal Implications and Effect of Court Decisions Relating to that Act, and His Opinions Do Not Meet the Requirement Of Reliability Necessary for Them to Be Admitted into Evidence Under Commission Rule 3.43(b) and Rule 702 of the Federal Rules of Evidence

Mr. Pollock states in his expert report (p. 3) that he has

> been asked by counsel for Upsher-Smith to evaluate the expert report of Joel E. Hoffman and render an opinion as to its accuracy. In particular, I have been requested to provide my opinion as to the state of 180-day exclusivity rights (including triggering of those rights), and industry perception of those rights, at the time of the agreement between Schering-Plough and Upsher-Smith, dated June 17, 1997, and at certain subsequent times.

While Mr. Pollock may be qualified to offer some limited testimony as to his understanding of the status of the Hatch-Waxman Act's 180-day exclusivity provision during the time he was at the FDA, and possibly may have some experience relevant to industry perception

regarding that issue, his total lack of formal training and limited relevant experience render him unqualified to offer expert opinions about the state of the law or the regulatory environment regarding the Hatch-Waxman Act or its 180-day exclusivity provisions at any time relevant to this proceeding. He likewise is unqualified by training or experience to evaluate the opinions about the Hatch-Waxman Act offered by Mr. Hoffman, Complaint Counsel's expert witness regarding FDA and Hatch-Waxman Act issues. Mr. Hoffman is a highly regarded attorney who, for nearly 30 years, has represented and counseled numerous clients on FDA regulatory law, including the Hatch-Waxman Act since its enactment in 1984. The opinions Mr. Hoffman offers in his report involve consideration of the changing status and interrelationship of statutes, regulations, and court decisions, and are dependent upon his knowledge and familiarity with the legal background concerning the Hatch-Waxman Act.

From even a casual reading of Mr. Pollock's report and [redacted] it is evident that all of the opinions and most of the statements Mr. Pollock offers concerning the Hatch-Waxman Act in fact involve interpretations of legal issues, statutes, regulations, and court decisions. [redacted] This training is unrelated to the opinions Mr. Pollock offers relating to the Hatch-Waxman Act. Nor has Mr. Pollock's experience, either at FDA or subsequently, provided him with special expertise to analyze and evaluate the legal environment regarding the Hatch-Waxman Act, and to render reliable opinions as an expert witness concerning 180-day exclusivity issues under the Hatch-Waxman Act, particularly at a time several years after he had left the FDA.

Mr. Pollock's expert report is replete with statements and conclusions that, as a non-lawyer with only limited experience regarding 180-day exclusivity issues under the Hatch-Waxman Act, he is unqualified by training or experience to offer as reliable expert testimony. That some of Mr. Pollock's opinions or statements may agree with those of Complaint Counsel's expert, Mr. Hoffman, is irrelevant to Mr. Pollock's qualification to offer such opinions. For example, Mr. Pollock states

> I generally concur with Mr. Hoffman's opinion that there was at least "substantial uncertainty" as to whether Upsher-Smith, an ANDA first filer settling its patent suit with the innovator, was entitled to 180-day exclusivity at the time of the agreement dated June 17, 1997. In fact, even a fully informed settling first filer would have had little or no reason to believe that it would enjoy such exclusivity. (Pollock report at 4)

This opinion regarding status of 180-day exclusivity under the Hatch-Waxman Act as of June 17, 1997, the date of the settlement agreement between Schering and Upsher-Smith, involves a complicated and difficult issue, as can be seen by its careful treatment in the expert reports of both Mr. Hoffman and Mr. Safir, Schering's expert witness on Hatch-Waxman Act issues. To reach a conclusion about this issue, an expert must consider and evaluate the legal import of numerous and often conflicting factors regarding the legal status of the relevant statute and its provisions, including certain regulations and other non-statutory guidance, and the interpretation, scope, and effect of various court decisions bearing on the issue. Mr. Pollock's absence of legal training or direct experience in construing statutes and case law immediately raise questions as to his expertise to do so here. Moreover, Mr. Pollock's FDA experience ended approximately two and a half years prior to the relevant time and prior to the critical court decisions relating to the issue of 180-day exclusivity under the Hatch-Waxman Act, and involved virtually no activity relating to such exclusivity issues. Likewise, his experience since leaving FDA has included

only limited involvement with Hatch-Waxman Act issues, of which 180-day exclusivity is only one of many. This experience provides a woefully inadequate basis for Mr. Pollock's claim of expertise on the exclusivity issue.

Mr. Pollock then goes on in his report (at 4-7) to discuss certain FDA regulations and other written guidance relating to the "successful defense" requirement under FDA regulations, an issue that was in litigation before, during, and after the Schering/Upsher-Smith settlement agreement. Throughout this section of his report, Mr. Pollock discusses the legal status and impact of various FDA regulations and guidance, as well the holdings and implications of numerous court decisions, including his opinions as to the holding and effect on FDA regulations of the district court decision in *Mova Pharmaceutical Corp. v. Shalala*, 955 F.Supp. 128 (D. D.C. 1997). As noted above, both the *Mova* decision and the settlement agreement at issue in this proceeding occurred more than two years after Mr. Pollock left the FDA. While his experience may provide him with some insight about the FDA's position on the successful defense requirement during his tenure at FDA, his experience provides no such expertise regarding this issue years after he left the FDA.

At p. 4 of his report, Mr. Pollock states that "[b]ecause Upsher-Smith settled its lawsuit and did not successfully defend it, under FDA regulatory provisions applicable at the time Upsher-Smith was not eligible for a 180-day exclusivity period." Insofar as this statement is nothing more than a factual assertion that, at the time of the Schering/Upsher-Smith settlement agreement, published FDA regulations included a successful defense requirement for 180-day exclusivity, it is unobjectionable (though not necessarily accurate) factual evidence, rather than expert opinion. However, if, as the subsequent discussion in Mr. Pollock's report makes clear,

this statement really is an opinion as to the continued applicability of that provision of the FDA's regulations to settling first ANDA filers (such as Upsher-Smith) in light of the *Mova* district court decision, then Mr. Pollock again is unqualified to reliably perform the legal analysis required to offer his opinion. Once again, nothing in his training, earlier FDA experience years before the *Mova* decision, or subsequent employment provides him with the expertise to reach such a law-based conclusion regarding the implications of this court decision on FDA regulations.

In his report (at pp. 6-7), Mr. Pollock discusses the legal implications of the *Mova* decision on first ANDA filers that settle their patent infringement litigation. He offers his opinion as to the legal implications of *Mova*, stating (at p. 7) that "*Mova* was of little guidance to an ANDA filer settling its patent lawsuit [such as respondent Upsher-Smith] because it concerned a first ANDA filer that was in the process of defending an infringement suit," without providing any explanation as to how or why he has reached this conclusion. This is particularly troubling given what the court in *Mova* did and said. The court in *Mova* enjoined the FDA from granting approval to a later filer's ANDA based on the first filer's failure to successfully defend its patent infringement lawsuit, as required by FDA's regulations. The court held that the Hatch-Waxman Act was clear on its face as to what was required for a first ANDA filer to qualify for 180-day exclusivity, and contained no requirement that the first filer successfully defend the litigation in order to have that exclusivity. The court went on to say that "indeed it [the statutory requirement for 180-day exclusivity] does not even require the institution of patent litigation." 955 F.Supp at 130. *A fortiorari*, a settling first filer meeting the Act's stated requirements for 180-day exclusivity cannot be denied that exclusivity by the FDA merely because it has settled

litigation in which the court in *Mova* concluded it was not even required to be engaged in the first place. Yet this is the apparently anomalous result that Mr. Pollock's unexplained interpretation of *Mova* says remains open after the *Mova* decision.

The status of the successful defense requirement at various times is a complex and difficult issue, requiring knowledgeable and careful analysis of the scope and implications of the court decisions in *Mova* and other cases. Mr. Pollock's unexplained conclusion on this issue, not based on legal or other relevant expertise or experience, is nothing more than the type of unsupported conclusion that the Supreme Court has held is properly excludable. (*See General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert").[4]

At pages 7-8 of his report, Mr. Pollock goes on to discuss the issue of a first filer's 180-day exclusivity under the Hatch-Waxman Act being triggered by a court decision finding the innovator's patent to be invalid or not infringed in a case involving a subsequent ANDA filer. Citing several court decisions, he states (at p. 7) that "[a] final decision of non-infringement or invalidity in any court action -- not just one against a first filer -- triggers the first filer's exclusivity period. The language of Hatch-Waxman has always permitted this interpretation." He later concludes (at p. 8) that

At all times after June 18, 1997, subsequent ANDA filers had reason to believe that they

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[4] "Ipse dixit" (Latin) - literally "he himself said it;" [*i.e.*, a "dogmatic statement supported by bare authority; dictum" (Mawson & Berlitz, *Dictionary of Foreign Terms* (2d ed. 1979));"an assertion by one whose sole authority for it is the fact that he himself has said it" (Gifis, *Law Dictionary* (1975);"a bare assertion resting on the authority of an individual" (Black, *Black's Law Dictionary* (rev. 4th ed. 1968)].

> could, through their own court actions, trigger a first filer's 180-day exclusivity. If the exclusivity period was triggered but the first filer was for some reason unable to enter the market, the exclusivity would nonetheless run and a subsequent filer could enter the market upon the expiration of the 180 days.

Again, this is a complicated issue implicating the Hatch-Waxman statute, FDA regulations, and court decisions, and about which Mr. Pollock is unqualified by training or experience to provide the court with reliable expert advice. His lack of training or experience in construing statutes and court decisions, and his at best very limited relevant professional experience provide no basis for his claim of expertise on this issue. As Mr. Pollock's own discussion of this issue makes clear, all of the relevant activity concerning this issue occurred no earlier than February of 1997, more than two years after Mr. Pollock left the FDA. (*See* Pollock Expert Report at 7-8). And nothing in his subsequent experience "providing expert technical advice to domestic and international client regarding U.S. Food and Drug Administration ("FDA") regulations, " including "requirements for approval of new prescription drugs, generic drugs, and prescription drug labeling" (Pollock Expert Report at 1) qualifies him to offer an expert opinion on this issue.

Were Mr. Pollock to hold himself out to the public as qualified to provide expert opinions regarding statutes and regulations, and the import and effect of various court decisions, as he does in his expert report, he would risk prosecution for the unlicensed practice of law. Yet he, and Upsher-Smith, seek to have his opinions regarding the Hatch-Waxman Act admitted as expert testimony in the present proceeding and relied upon by the court. Moreover, as discussed above, Mr. Pollock's professional experience, both while at the FDA, and subsequently, provide little or no support for his claim of expertise in this area. The events and issues he addresses in his report all occurred or arose long after he had left the FDA, and he has failed to demonstrate

that the limited relevant activity in his subsequent employment provides a sufficient basis for concluding that he is capable of providing reliable expert testimony on the issues addressed in his report. To allow Mr. Pollock to offer these "expert" opinions, and to "evaluate" Mr. Hoffman's expert report on matters involving complicated legal issues and "render an opinion as to its accuracy," would be to allow the most unreliable and unhelpful "expert" testimony into evidence, and would eviscerate the evidentiary requirement that expert testimony be reliable in order to be properly admissible in Commission adjudicative proceedings.

III. Mr. Pollock is Not Qualified to Render an Expert Opinion Regarding the Competitive Nature of the Schering/Upsher Smith Settlement Agreement, or its Provision Precluding Generic Entry By Upsher-Smith Before September 1, 2001, and His Opinion Does Not Meet the Requirement Of Reliability Necessary for It to Be Admitted into Evidence Under Commission Rule 3.43(b) and Rule 702 of the Federal Rules of Evidence

At page 3 of his report, Mr. Pollock states that "I was also asked to determine whether the [Schering/Upsher-Smith patent infringement lawsuit settlement] agreement appeared to be pro-competitive or anticompetitive," and in paragraph 3 of his report (pp. 8-9), he makes the sweeping conclusion that "the settlement agreement actually appears to be pro-competitive in nature," based on its provision permitting Upsher-Smith to enter the market with a generic product on September 1, 2001, prior to the expiration of Schering's patent on the product in 2006. However, at his deposition, [redacted]

[redacted]

Nowhere in his report [redacted] did Mr. Pollock indicate that he had considered any of the other terms or provisions of the Schering/Upsher-Smith settlement agreement, and whether these other terms were procompetitive or anticompetitive, or rendered the overall settlement agreement anticompetitive on balance, despite its provision for generic entry in 2001.

[redacted] As a non-lawyer, Mr. Pollock is certainly not an expert in patent law and settlement of patent infringement litigation, and he testified at his deposition that [redacted]

[redacted]

[redacted] Whatever his qualifications as an expert on "FDA/Hatch-Waxman," Mr. Pollock and Upsher-Smith have neither designated Mr. Pollock as a "consumer" expert, nor established any qualifications for Mr. Pollock's offering an expert opinion as a consumer or consumer representative, even assuming that such an area of expertise meeting the requirements for admissibility exists.

In describing his understanding of the task of opining on the competitive nature of the settlement agreement, Mr. Pollock testified at his deposition that [redacted] Thus it is not even clear to which benchmark Mr. Pollock was comparing the generic entry date under the Schering/Upsher-Smith settlement agreement in reaching his conclusion that the generic entry provision was "procompetitive."

Complaint Counsel went on to explore in his deposition [redacted]

Complaint Counsel also attempted to identify [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Nowhere in his report does Mr. Pollock consider whether generic entry might have occurred earlier than September 1, 2001, if the settlement agreement had not included payment of $60 million to Upsher-Smith as part of the settlement, and whether, under this benchmark of comparison, he would consider the provision for a September 1, 2001 generic entry date procompetitive.

When asked [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] Mr. Pollock testified at his deposition that [redacted] This apparently crucial information is not even mentioned in his expert report, and nowhere in his expert report [redacted] does Mr. Pollock establish that such [redacted] information [redacted] is the type of information "reasonably relied upon by experts in the particular field in forming opinions" on such issues. The Commission previously has applied Rule 703 in excluding expert testimony based on similar

unreliable and potentially biased information prepared by an interested party.[5] Given the inadequacy and unreliability of the information relied upon by Mr. Pollock, and the failure to meet the requirements of Rule 703 regarding the underlying information he relied upon in forming his opinion on the competitiveness of the Schering/Upsher-Smith settlement agreement, his opinion on this issue is fatally flawed and is not properly admissible into evidence.

In summary, the analysis undertaken by Mr. Pollock to reach his conclusion concerning the procompetitiveness of the Schering/Upsher-Smith settlement agreement is wholly inadequate for his opinion on this issue to be considered reliable expert testimony under Rule 702 of the Federal Rules of Evidence, and to be admissible under the Commission's Rules. [redacted]

[5] *See In re Olin Corporation*, 113 F.T.C. 400 at 600-602 and n. 13, 1990 FTC Lexis 234, holding that statistical information compiled specifically for trial by an Olin employee for, and at the request of, an Olin expert witness was properly excluded by the ALJ because it: (1) was not an ordinary business record subject to a hearsay exception, and could not be evaluated as to its reliability; and (2) did not meet the requirement of Rule 703 of the Federal Rules of Evidence that the data relied on by an expert be "of a type reasonably relied upon by experts in the particular field."

[redacted] To allow into evidence Mr. Pollock's opinion on this issue as reliable expert testimony under these circumstances would render the requirement of reliability for expert testimony a nullity.

IV. Mr. Pollock is Not Qualified to Render an Expert Opinion Regarding Whether or Not the New Drug Application (NDA) for Upsher-Smith's Niacor-SR Would or Would Not Have Been Approved by the FDA, and His Opinion Does Not Meet the Requirement Of Reliability Necessary for It to Be Admitted into Evidence Under Commission Rule 3.43(b) and Rule 702 of the Federal Rules of Evidence

Complaint Counsel previously have filed a Cross-Motion in Limine to Exclude Expert Testimony on FDA Approval of Niacor-SR by all of Respondents' expert witnesses in this matter. However, even if such testimony is not broadly excluded, the testimony of Upsher-Smith's expert witness - Robert Pollock – on this issue nevertheless should be excluded as unreliable and not properly admissible under the Commission's Rules and the Federal Rules of Evidence.

On page 3 of his expert report, Mr. Pollock states that he was asked to render an expert opinion on "whether there were significant barriers which would have precluded FDA approval of Niacor SR." In paragraph 5 of his report, on page 9, Mr. Pollock provides his opinion and entire expert analysis: "Based on the information presently available to me, I do not have reason

to believe that Upsher-Smith's Niacor SR would have failed to receive FDA approval." The only documents reviewed by Mr. Pollock that appear to relate to this issue are the last four items referenced on page 13 of his report, including a log of correspondence between Upsher-Smith and the FDA, certain correspondence between Upsher-Smith and FDA, and two draft study protocols for Niacor-SR ••••••••••••••••

Mr. Pollock is entirely unqualified to render a reliable opinion as to whether the FDA would have granted approval to Upsher-Smith's NDA for Niacor-SR. At his deposition, •••••

[redacted]

Mr. Pollock has utterly failed to meet Rule 702's requirements that an expert opinion be based on "sufficient facts or data," be "the product of reliable principles and methods," and resulted from his having "applied the principles and methods reliably to the facts of the case." The very limited and incomplete information Mr. Pollock considered in rendering his opinion as to the likely approval of the NDA for Niacor-SR is a wholly inadequate basis for offering an expert opinion on the issue under Rule 702, and Mr. Pollock has not shown that the limited information on which he relied is the type of information that experts in his field reasonably rely on in forming opinions on whether an NDA is likely to be approved by the FDA.

Moreover, [redacted] in his expert report [redacted] Mr. Pollock has failed to explain how his "experience" provides a sufficient basis for his conclusion. As discussed previously, the Advisory Committee Notes to Rule 702 explain that Rule 702 requires that "[t]he expert's testimony must be grounded in an accepted body of learning or experience in the expert's field, and the expert must explain how the conclusion is so grounded." Mr. Pollock has totally failed to identify any such accepted body of learning or experience in his field, has considered woefully inadequate facts in making his evaluation and reaching his conclusion, and has failed to explain how his conclusion is grounded in, and results from, reliable application of adequate facts to a reliable and accepted analytical methodology. These gross deficiencies render

Mr. Pollock's opinion as to the likely approval of Niacor-SR entirely unreliable and thus his opinion must be excluded under the Commission's Rules.

V. Conclusion

For the reasons discussed above, we believe that Mr. Pollock is not qualified by training, knowledge, or experience to render reliable expert opinions regarding the issues discussed above. We therefore respectfully request that this Court grant Complaint counsel's Motion in Limine to exclude from evidence in this proceeding, as required by § 3.43(b) of the Commission's Rules, Mr. Pollock's expert testimony, including both testimony at trial and his testimony contained in his expert report, relating to the Hatch-Waxman Act or any provision or aspect thereof, including the Act's 180-day exclusivity provision, the competitiveness of the Schering/Upsher-Smith patent infringement litigation settlement agreement, or any aspect thereof, and the issue of possible approval or disapproval by the FDA of Upsher-Smith's new drug application (NDA) for Niacor-SR.

Respectfully submitted,

Karen G. Bokat
David M. Narrow
Counsel Supporting the Complaint

Dated: January 8, 2002

UNITED STATES OF AMERICA
BEFORE 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

ORDER GRANTING COMPLAINT COUNSEL'S MOTION *IN LIMINE* TO EXCLUDE EXPERT TESTIMONY OF ROBERT W. POLLOCK

IT IS HEREBY ORDERED that complaint counsel's motion *in limine* to exclude expert testimony by Robert W. Pollock at trial or in his expert report concerning or relating to: 1) the Hatch-Waxman Act or any provision or aspect thereof, including particularly the Act's 180-day exclusivity provisions; 2) any competitive assessment of the agreement, or any aspect of that agreement, between Upsher-Smith Laboratories, Inc. ("Upsher") and Schering-Plough Corporation ("Schering") settling the patent infringement litigation between them concerning K-

Dur; and 3) the issue of possible approval or disapproval by the FDA of Upsher-Smith's New Drug Application ("NDA") for Niacor-SR, is granted.

Dated: _____, 2002

_____
D. Michael Chappell
Administrative Law

CERTIFICATE OF SERVICE

I, David M. Narrow, hereby certify that on January 8, 2002, caused two copies of the public version of the Complaint Counsel's Motion *In Limine* To Exclude Expert Testimony of Robert W. Pollock, the Memorandum In Support thereof, and the Proposed Order, to be served upon the following person by hand delivery:

Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission, Rm. H-104
600 Pennsylvania Avenue, NW
Washington, DC 20580

I caused one original and one copy of the public version of the Complaint Counsel's Motion *In Limine* To Exclude Expert Testimony of Robert W. Pollock, the Memorandum In Support thereof, and the Proposed Order, to be served by hand delivery and email upon the following Office:

Office of the Secretary
Federal Trade Commission,
600 Pennsylvania Avenue, NW
Rm. H-104
Washington, DC 20580

I caused one copy of the public version of the Complaint Counsel's Motion *In Limine* To Exclude Expert Testimony of Robert W. Pollock, the Memorandum In Support thereof, and the Proposed Order, to be served by hand delivery to the following parties:

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