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 OPPOSITION TO COMPLAINT COUNSEL'S MOTION TO LIMIT OR EXCLUDE EXPERT WITNESS TESTIMONY

Respondent Schering-Plough Corporation ("Schering") respectfully submits this memorandum in opposition to complaint counsel's motion to limit Schering's ability to present expert testimony[1]. Complaint counsel contends Schering's defense should be limited on the ground that testimony by some of its experts may be duplicative or inadmissible. However, the testimony of each of Schering's experts is important to its defense, and any duplication is minimal. Schering, therefore, requests that complaint counsel's motion be denied.[2]

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1 *See* Motion To Limit or Exclude Duplicative and Improper Expert Witness Testimony ("Motion").

2 Schering does not oppose complaint counsel's Motion insofar as it requests that Schering designate either Mr. Kenneth McVey or Dr. Zola Horovitz as an expert on the reasonableness of the licensing fee for Niacor-SR. Schering agrees to exclude Mr. McVey from its list of experts who will testify at trial. In return for Schering's consent on this matter, Schering expects that complaint counsel will withdraw its designation of portions of Mr. McVey's deposition and will not use such deposition designations at trial.

A. The Expected Testimony of Schering's Experts

1. Experts on the Negotiation of Settlements

The Complaint in this case challenges the settlement of two patent infringement lawsuits brought by Schering—one against Upsher-Smith ("Upsher") and the other against ESI-Lederle ("ESI"). Each settlement included licensing transactions involving products that were unrelated to the litigation. Complaint counsel suggests that such transactions unrelated to the matters in litigation, but entered into simultaneously with the settlements, are inherently suspicious. (May 1, 2001 Hearing Tr. 8). In fact, however, expert negotiators and mediators have long believed that exploring value-creating transactions outside the matters in dispute in the litigation is a beneficial technique for facilitating settlements. There is nothing unusual or suspicious about such transactions.

Schering will offer the testimony of two experts with broad experience in the field of settlement negotiations and mediation to explain why settlements are facilitated by transactions, such as the licenses that were entered into by Schering and Upsher and Schering and ESI, involving products unrelated to the dispute.

Professor Mnookin

Professor Robert Mnookin is an academic. He teaches negotiation at the Harvard Law School, and is the Director of the Harvard Negotiation Project. He will testify that use of value-creating transactions unrelated to the litigation is a highly recommended way of settling intractable disputes. He has written books advocating use of such transactions to facilitate settlements; and he will testify that he teaches students in his negotiation courses to explore such value-creating trades outside the subject matter of the litigation when negotiating a settlement. He will also testify that there are sound policy reasons for permitting parties to do this, and that any rule that would prohibit such arrangements would seriously impede the settlement process.

Mr. O'Shaughnessy

James O'Shaughnessy is a practicing patent litigator, an experienced arbitrator and trained mediator, and a business executive. In each of these capacities, Mr. O'Shaughnessy has had wide-ranging experience in the settlements of patent litigation. He will testify that he has made extensive use *in practice* of the concepts endorsed by Professor Mnookin. He will testify that parties involved in settlement negotiations of patent litigations frequently hold polarized views about the litigation, and that exploring business arrangements having nothing to do with the matters in dispute often works to bridge the gap. He will testify that use of this settlement technique is common.

Mr. O'Shaughnessy will also give very important testimony in rebuttal to complaint counsel's expert economist, Timothy Bresnahan. Mr. Bresnahan has no experience in negotiation of settlements. Nonetheless, Mr. Bresnahan has rendered an intricate thirty-page analysis of patent settlements, based entirely on untested *economic theory*. He opines that [

] Mr. O'Shaughnessy will testify that real world settlement negotiations simply do not proceed in accordance with Professor Bresnahan's economic theories.[3]

[3] Indeed, complaint counsel's own rebuttal expert on negotiations agrees with Mr. O'Shaughnessy on this point. *See* Deposition of Max H. Bazerman at [:

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Thus Mr. O'Shaughnessy will testify that the merits of the patent case must be examined before one may reliably make a judgment about whether a settlement is better or worse for consumers than continued litigation.

2. Experts on Matters Related to the Value of the Products Schering Licensed from Upsher-Smith

As Schering explains in its motion in limine regarding the testimony of complaint counsel's licensing expert, Dr. Nelson Levy, Dr. Levy opines on a number of different issues in an effort to support his conclusion that [

] Schering, which has agreed to withdraw the testimony of one of the experts it designated to respond to Dr. Levy, plans to offer the testimony of two experts in response to Dr. Levy: Dr. Zola Horovitz and James Furniss.

Dr. Horovitz

Dr. Horovitz has 40 years' experience in the pharmaceutical industry, 35 in various positions at Bristol-Myers Squibb. For several years before his retirement from Bristol in 1994, Dr. Horovitz was the vice president in charge of pharmaceutical licensing, business, and commercial affairs. Previously, he served as the vice president in charge of research, and the vice president in charge of drug development. Thus, unlike Dr. Levy, Dr. Horovitz has expertise in the areas of *both* pharmaceutical science and research *and* pharmaceutical marketing and licensing. Again unlike Dr. Levy, Dr. Horovitz has experience in licensing products for European markets.

Dr. Horovitz will offer testimony in response to a number of different opinions by Dr. Levy. He will testify that, in his opinion, the rights that Schering acquired from Upsher to market Niacor-SR overseas were worth considerably more than what Schering paid. He will testify that Schering's decision to make payments totaling $60 million for these rights was amply supported by the clinical information provided to Schering by Upsher.

James Furniss

Dr. Levy made a specific issue about the price Schering would have been able to charge for Niacor-SR in Europe's partly price regulated markets. Dr. Levy opined that [

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Dr. Levy has absolutely no experience that would qualify him to render this opinion. Nonetheless, since he raised the issue, Schering will offer the expert testimony of James Furniss, a witness specially qualified to address this issue. From 1989 to 1997, Mr. Furniss worked for the Department of Health in the United Kingdom, where his responsibilities at various times included the determination of pricing for generic medicines and participation in pricing decisions for prescription pharmaceuticals. He gained a detailed understanding of the pricing and reimbursement structures for the various member states of the European Union while representing the United Kingdom on the European Commission's Pharmaceutical Pricing Transparency Committee. In his current position as Senior Vice President of Cambridge Pharma Consultancy, Mr.Furniss advises companies on strategies to gain commercially successful pricing and reimbursement for new pharmaceutical products, primarily in European markets. Mr. Furniss will testify that Schering's pricing assumptions for Niacor-SR were fully justified. He will also address a number of misconceptions in the report of Dr. Levy regarding [ ]

3. Schering's Economic Experts

Complaint counsel's economic expert, Professor Bresnahan, intends to testify that, [

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Professor Bresnahan's opinion in this regard is inconsistent with that of many respected economists, including Dr. Richard Gilbert, formerly the Chief Economist of the Antitrust Division of the Department of Justice. Dr. Gilbert was involved in the creation of the Antitrust Guidelines for the licensing of intellectual property. He has not been retained by any of the parties to this matter. He has expressed a view that is squarely at odds with Dr. Bresnahan's. In Dr. Gilbert's opinion, "[t]he fact that a settlement involves a payment from the patentee to the challenger is not sufficient to determine that the settlement is anticompetitive." Richard Gilbert and Willard Tom, *Is Innovation King at the Antitrust Agencies? The Antitrust Guidelines Five Years Later*, 69 Antitrust L.J. 43, 78 (2001).

Professor Willig

Schering's expert economist, Professor Willig, will testify to three basic propositions important to Schering's defense. First, he will testify that splitting the remaining life of the patent, without a payment, poses *no* threat of anti-competitive harm to consumers. (Willig Exp. Rep. 3, 9). Second, Professor Willig will testify that settlement agreements that split the remaining patent life and which also involve transactions unrelated to the litigation present no threat of anticompetitive harm to consumers so long as those transactions are for fair value, (*Id.* at 3, 11). Third, Professor Willig will testify that it is not possible to determine whether a particular settlement that sets the date of entry by a generic is anticompetitive simply by reference to whether the settlement included a payment. Professor Willig will testify that Professor Bresnahan's

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] is simply wrong as a matter of economic theory. Instead, Professor Willig will testify that it is necessary to address the merits of the patent case, and compare the settlement to the likely outcome of that case. Professor Willig will

demonstrate his conclusions through a series of mathematical and theoretical models that he developed to show that settlement agreements that set the date of generic entry are not necessarily anticompetitive even if accompanied by a payment.[4]

Dr. Addanki

Dr. Summanth Addanki, Schering's other economist expert, will define the relevant market in which Schering's K-Dur 20 competes, and testify as to the reasons why Schering has not been shown to have monopoly power in that market. He will explain that monopoly power is an essential element of complaint counsel's theory of this case, as described by Professor Bresnahan, and will point out that that element is not established by anything Professor Bresnahan says in his report. Dr. Addanki will testify that K-Dur 20 faced competition in 1997, at the time of the settlement, from over twenty other potassium chloride products. These products consisted mainly of potassium chloride supplements in the 10 mEq dosage form. Schering's K-Dur 20 had a marketing advantage because its pills were in a 20 mEq dosage form and were unique in that respect. Consumers, however, could quite easily take two 10 mEq pills instead of one K-Dur 20. Schering did not charge a premium price for its 20 mEq tablet over the brand name 10 mEq competitors. And there were low-priced generic versions of some of the

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[4] Once again, complaint counsel's negotiation witness, Mr. Bazerman, supports the position of Schering's experts and contradicts Professor Bresnahan. Thus, Mr. Bazerman states:

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10 mEq brand name products. Dr. Addanki will testify that K-Dur's market share—less than 40 percent—was likely the result of Schering's superior marketing and promotion of the product, not monopoly power. Dr. Addanki will point out that Schering did not have the ability to charge a premium price for K-Dur 20, which is evidenced by the fact that it was priced lower than two 10 milliequivalent products.

Dr. Addanki will also testify that, in his opinion, there are numerous circumstances in which a settlement that splits the remaining patent life—and also involves a payment—will not be anticompetitive. All of the facts must be explored, including the merits of the patent case and its likely outcome to determine whether such a settlement is anticompetitive. Dr. Addanki will then perform an analysis that compares the settlements to possible litigation outcomes.

It is very important to Schering to be able to present expert testimony both on economic models demonstrating the flaws in Professor Bresnahan's economic theory, which Professor Willig has developed; and on issues related to competition and Schering's lack of monopoly power, proof of which Dr. Addanki has developed. This testimony is not duplicative and should be admitted.

4. Schering's Patent Experts

As set forth above, an objective assessment of the merits of the underlying *ESI* and *Upsher* cases is relevant to the issues in this case. The parties to any litigation have a right to resolve that litigation by settlement, with the plaintiff accepting less than all the relief sought in the lawsuit. Here, Schering compromised and settled its claims in both cases by agreement, permitting Upsher and ESI to enter the market much sooner than if Schering had prevailed in the litigation. And, under the antitrust laws parties may settle a *bona fide* patent dispute so long as the settlement "[is] not more anticompetitive than a likely outcome of [the] litigation." 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2046 at 265-66 (1999).

In order to determine whether the settlements at issue in this case were anticompetitive—*i.e.*, whether they harmed competition and consumers—it is necessary to ascertain the strength of Schering's litigating position in each patent case. Only then may the settlement be compared to the likely outcome of the litigation. This will help the Court determine whether a well-informed and well-counseled consumer would have preferred the settlements—each of which permitted generic competition well before Schering's patent expired—or whether a well-informed and well-counseled consumer would have preferred taking his or her chances on continued litigation.

To that end, Schering is prepared to call four witnesses. Three of the witnesses, Dr. Gilbert S. Banker, Dr. Robert S. Langer, and Mr. Gerald H. Bjorge, were expert witnesses in the underlying *ESI* and *Upsher* cases. These witnesses offered expert reports and declarations that formed important parts of the actual evidence in those cases. In the FTC hearing, these witnesses will testify as to the opinions and evidence they *actually offered* in the underlying *ESI* and *Upsher* cases. Their testimony will help the Court understand and make a judgment about the likely outcome of the patent cases.

It bears emphasis that complaint counsel has not contested Schering's right to introduce evidence concerning the strength of its patent cases. No motion in limine challenging the relevance of such evidence has been filed, and complaint counsel has identified several experts of its own to testify in rebuttal on this same issue. What complaint counsel has done instead is to file a motion in limine which seems to be designed to prevent proof on this subject from being presented in a way which will be efficient and understandable.

Dr. Banker

The K-Dur patent at issue in both cases covered a method of coating potassium chloride to control the delivery of potassium in the body, over time. Dr. Banker is a former dean of several major pharmacy schools and an expert in drug delivery and coating systems. Dr. Banker has written the leading treatise and hundreds of scholarly

works in the field of drug coatings. He will provide the Court with the expert analysis that he offered as to the issues in the *ESI* and *Upsher* cases.

Dr. Langer

Schering's patent calls for a mixture of the coating ingredients. In the *ESI* case, ESI's defense rested on its contention that the two coating ingredients specified in Schering's patent were *not mixed* when applied in ESI's product. Dr. Langer is a professor at MIT who conducted scientific tests and established that the coating material in ESI's product *were mixed.* This evidence proved that ESI's product infringed the Schering '743 patent. In this case, Dr. Langer will testify about the tests that he conducted and that he was prepared to testify at the trial of the *ESI* case.

Mr. Bjorge

Mr. Bjorge is a patent lawyer who offered expert testimony as to patent issues in the *ESI* and *Upsher* cases. At the time those two cases were litigated, the use of patent law experts in patent litigation was common. Indeed, in the *ESI* case, both parties retained patent law experts.[5] All parties involved in the two underlying cases provided expert testimony as to claim construction in connection with summary judgment motions and related motions.[6] In the present case, Mr. Bjorge's testimony will relate for this Court the testimony he actually gave in his reports and declarations in the *ESI* and *Upsher* cases.

Mr. Miller

Schering's fourth witness is Mr. Miller. Mr. Miller is a partner at the patent law firm of Pennie & Edmonds, LLP. Mr. Miller also holds a Ph.D. in Chemistry. He has

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5 In the *ESI* case, the expert opinion of Mr. John F. Witherspoon, a patent attorney, was proffered on the issues of non-infringement, patent validity, and damages.

6 Expert testimony of Dr. Harold B. Hopfenberg was proffered on the issue of claim construction, patent infringement and validity in the ESI case. Similarly, Dr. Rhodes offered expert testimony on claim construction in the Upsher case.

been an active patent litigator, arbitrator, and special master and is deeply versed in evaluating patent litigation and analyzing the likely outcomes of patent litigation.

Mr. Miller will function as a summary witness, to summarize and evaluate the evidence in the two cases. He has reviewed essentially the entire record of the *Upsher* and *ESI* cases, including the depositions and pleadings. He is in a position to summarize for this Court all of the important evidence in the record in both cases, and to render an opinion – in light of the evidence and the applicable patent law – as to the strength of Schering's case and Upsher and ESI's defenses. Mr. Miller is prepared to opine as to whether the split of the patent term in the Upsher and ESI settlement agreements fairly reflects the likely outcome of the two cases. Miller's detailed review of the record in these two cases should be most helpful to the court in assessing the merits of the two patent cases. No other witness can provide such helpful testimony to the Court. Not only has Mr. Miller reviewed substantially the entire record in those two cases, he can assist the Court by providing the unique perspective on the facts from one who is both a senior partner at a major patent firm and who holds a Ph.D. in the relevant art.

Thus, three of Schering's four experts will provide the testimony and opinions that they were prepared to provide in the trial of the underlying cases, and which they did provide in reports and depositions in those cases. They will essentially describe the evidence upon which the parties' decision to settle was based. Any objective assessment of the merits of the *ESI* and *Upsher* cases must consider such evidence. Mr. Miller will give helpful, detailed, and non-cumulative testimony as to the remaining evidence and contentions in those cases, and as to the likely outcome of the two patent cases and how those likely outcomes relate to the split of the patent life in the Upsher and ESI settlements. There is no basis to strike any of this testimony.

B. Schering's Expert Testimony Should Be Permitted

Over the past year, complaint counsel has had the unrestricted ability to discover and make its case. This has consumed significant amounts of time for all parties. Complaint counsel has taken approximately 42 depositions just of Schering witnesses, totaling approximately 6279 pages of deposition testimony.[7] It has required Schering to search for and produce tens of thousands of documents. Now complaint counsel moves to limit Schering's ability to present a defense, primarily on the ground that Schering's defense will take too much time. Complaint counsel's motion should be denied.

Commission Rule 3.41 (c) provides that "[e]very party, except intervenors, whose rights are determined under § 3.14, shall have the right of due notice, cross examination, *presentation of evidence*, objection, motion, argument, and all other rights essential to a *fair hearing*." 16 C.F.R. § 3.41(c) (emphasis added). Schering will call its witnesses who were involved in the settlements live at the hearing. Schering will also present the testimony of experts to respond to complaint counsel's contentions, and to the testimony and conclusions of complaint counsel's experts. As set forth above, their testimony is both necessary and important to Schering's defense, and, we believe, to the Court's understanding of the issues.

1. Testimony By Schering's Experts Is Not Impermissibly Duplicative

As set forth above, the testimony of Schering's experts is not impermissibly cumulative. Courts routinely deny motions to exclude expert testimony, even where multiple experts testify about the same issue, where there are substantive differences between the perspective taken, methodology used, or aspects of an issue addressed by each expert. *See, e.g., Colon v. BIC USA, Inc*, 2001 U.S. Dist. LEXIS 21037, *103-104 (S.D.N.Y. 2001) (testimony of three experts regarding whether a lighter latch had been

[7] For reasons difficult to fathom in a case which will turn on issues of intent and credibility, complaint counsel does not intend to call live *any* of the witnesses who were involved in the settlements challenged by the complaint.

removed was not cumulative because each expert conducted different tests in reaching his conclusion); *Industrial Hard Chrome*, 92 F. Supp. 2d at 791 (testimony of experts was not cumulative because experts testified on different aspects of device at issue); *Coles v. Jenkins*, 34 F. Supp. 2d 381, 383 (W.D.Va. 1998) (testimony of three experts who opined on identical issue of road dangerousness was not cumulative because each expert had different area of expertise).

To the extent that there is any undue duplication of conclusions or testimony by Schering's experts, it can easily be dealt with at trial. *See Robinson v. Thomas*, 1995 U.S. Dist. LEXIS 15078 (N.D. Ill. 1995); *Pacific Employers Ins. Co. v. P.B. Hoidale Co., Inc.*, 782 F. Supp. 564 (D. Kan. 1992).

2. The Testimony of Two Patent Case Lawyer Experts is Not Excludable

Complaint counsel raises a discrete objection to the testimony of two lawyer experts on the ground that, in complaint counsel's view, they may testify on issues of law for the Court. We cannot help noting at the outset that this is an odd objection coming from complaint counsel. One of the three experts complaint counsel will call in its case-in-chief, Mr. Joel Hoffman, is a lawyer who will testify on pure questions of law, *i.e.*, what FDA law was and is on the subject of the 180-day exclusivity for first generic filers. Further, complaint counsel has designated a patent lawyer expert of its own to testify in rebuttal as to the merits of the patent case.

In any event, complaint counsel's objection should be rejected. Most of the testimony of Schering's patent lawyer experts will be a summary and analysis of the facts and evidence in each patent case. This will be by far the most efficient way of familiarizing this Court with the facts and the record in the underlying patent case. And, to the extent legal matters are touched upon in these experts' testimony, there is abundant authority permitting such an expert to touch on legal issues where to do so will assist the

court.[8]

Patent lawyers are uniquely qualified to provide opinions as to the likely outcome of a patent case -- they do it every day to advise their clients. Without the use of such an expert in this matter, it would probably be necessary for Schering to offer all of the patent evidence from the two cases into the record and have the Court form its own opinion as to the likely outcome of the case, unaided by the parties' summary witnesses. Instead, the expert testimony from Mr. Miller greatly simplifies the evidence-taking in this case, as he has reviewed substantially the entire record in both cases, and can synthesize that evidence while at the same time evaluating it with the expertise that patent lawyers possess as to how patent litigation is likely to be resolved.

Complaint counsel relies on factually inapposite cases that merely find expert testimony on legal opinion unhelpful on the particular facts of the individual cases. For example, complaint counsel cites several non-patent cases for the proposition that expert testimony is unhelpful on legal issues.[9] However, it is well established that the Court has wide discretion to accept expert testimony on legal issues if it is relevant and helpful. *See, e.g., Peckham v. Continental Casualty Ins. Co.* 895 F.2d 830, 837 (1st Cir. 1990) (affirming trial court's decision to admit expert testimony by attorneys regarding whether insurer's bad faith was proximate cause of excess judgment in personal injury case because experts "could reasonably be expected to shed some light in a shadowy domain [of insurance law]"); *Karns v. Emerson Elec. Co.*, 817 F.2d 1452, 1459 (10th Cir. 1987) (affirming trial court's decision in products liability case to admit expert testimony that included legal opinions that product was "unreasonably dangerous beyond the

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[8] Another legal issue, namely the correct interpretation of the FDA's 180-day exclusivity rule, has already been found by this Court to be a fact issue as to which expert testimony is appropriate in this case. Order Denying Motions of Respondents Schering-Plough and Upsher-Smith to Dismiss the Complaint, entered on October 31, 2001, at 10. The outcome of the patent cases is a fact issue in this case in a directly analogous fashion.

[9] *E.g., Burkhart v. WMATA*, 112 F.3d 1207 (D.D.C. 1997); *Specht v. Jensen*, 853 F.2d 805 (10th Cir. 1988)

expectation of the average user" and that defendant acted "recklessly" in producing and distributing it); *United States v. Gold*, 743 F.2d 800, 816-17 (11th Cir. 1984) (affirming trial court's decision to admit expert testimony in Medicare fraud case that certain claims made by defendants were beyond the scope of Medicare's coverage); *Huddleston v. Herman & MacLean*, 640 F.2d 534, 552 (5th Cir. 1981) (affirming trial court's decision in securities fraud case to admit expert testimony of attorney concerning interpretation to be given to certain language in defendants' prospectus); *Marketing One Partners v. The Liberty Corp.*, 1998 U.S. Dist. LEXIS 17805 (E.D.N.C. Sept. 8, 1998).

Marketing One Partners is instructive. There, the plaintiff, Marketing One, sued the defendant, Liberty Corporation ("Liberty") for breach of a contract for Marketing One's sale of an insurance company to Liberty. One of the reasons Liberty offered in defense of its termination of the sale contract is that the transaction would not have received the prerequisite approval from the North Carolina Department of Insurance ("NCDI"). Marketing One proffered testimony by two experts on the regulatory decision-making process, including whether NCDI would have approved the Marketing One-Liberty transaction. Liberty moved to exclude this testimony on the ground, *inter alia*, that it presented improper legal conclusions. 1998 U.S. Dist. LEXIS 17805, *14-*16.

The court denied Liberty's motion, noting that "courts often allow experts to testify on legal issues, so long as their testimony relates to a material fact in the case and is helpful to the jury." *Id.* at *18. The court explained that, in order to reach the conclusion that the NCDI would have approved the Marketing One-Liberty transaction, plaintiff's experts "attempted to recreate the analytical process that the NCDI would have used to analyze the deal. They applied regulations to facts and reached a legal conclusion." *Id.* at *19. The court held that this testimony was admissible because the experts' conclusion would help the jury to determine a material fact in the case and

would assist the jury in deciding whether Liberty had made its "best efforts" to complete the Marketing One-Liberty transaction. *Id.* at *20.

With regard to legal experts in patent cases, complaint counsel's position is contradicted by the writings of its own patent law expert in this case. Complaint counsel's patent law expert in this case has written that "the law on the use of patent law and procedure experts in patent infringement litigation is that their use is solely within the discretion of the trial judge." Martin J. Adelman, *The Role of the Expert in Patent Litigation*, J. Proprietary Rights, Vol. 10 at 2 (1992). In his deposition, Mr. Adelman conceded that [

]. (Adelman Dep. at).

A number of decisions of the U.S. Court of Appeals for the Federal Circuit have specifically recognized the wide discretion of the trial judge to accept or reject expert legal testimony. For example in *Markman v. Westview Industries, Inc.*, 52 F.3d 967, 983 (Fed. Cir. 1995), the court stated that "as to these types of [expert legal] opinions, the court has complete discretion to adopt the expert legal opinion as his own, to find guidance from it, or to ignore it entirely, or even to exclude it." *Accord, Becton Dickinson & Co., v. C.R. Bard, Inc.*, 922 F.2d 792, 797 (Fed.Cir. 1990); *Acoustical Design Inc. v. Control Electronic Co.*, 932 F.2d 939 (Fed. Cir. 1991); *Beckman Instruments v. LKB Produkter AB*, 892 F.2d 1547 (Fed.Cir. 1989).

At the time of the *ESI* and *Upsher* cases, the use of patent law experts to testify as to mixed questions of law and fact, such as validity and infringement, was common. One contemporaneous review article, noted:

> The discipline of patent law is considered by many in the profession to be among the most complex, requiring a good deal specialized knowledge. In addition, the technical nature of the factual situations addressed by the patent law, requires even further knowledge on the part of patent practitioners. *Such considerations have made the use of experts a major component of patent litigation.*

H. Pollock, *The Admissibility and Utility of Expert Legal Testimony in Patent Cases*, 1992 IDEA: J. Law and Technology 361, 363 (1992)(emphasis added). The Pollack article also surveyed the cases in which the Federal Circuit had affirmed decisions in which patent law expert testimony played a major role. Pollack likewise noted that "a trial judge is afforded a good deal of discretion in making a determination that such testimony will be of aid to the trier of fact." *Id.*

The other authorities cited by complaint counsel in no way support the exclusion of the Miller and Bjorge testimony in this case. Complaint counsel cites the decision in *Visx, Inc.*, FTC Dkt. No. 9286 (May 27, 1999) for the proposition that expert testimony in that case was limited to the procedures of prosecuting a patent before the Patent and Trademark Office. (Complaint counsel Br. at 14-15). However, review of the decision shows that the *only issue* that was tried in the case related to alleged inequitable conduct in the procurement of the patent. Hence, *Visx, Inc.* stands for nothing more than the obvious proposition that the patent expert testimony should be tailored to be relevant to the issues actually tried. Similarly, it is apparent from the opinion in *In re Cardizem CD Antitrust Litigation*, 105 F.Supp.2d 682 (E.D. Mich. 2000), that the court had already ruled against the party proffering the expert testimony on the issue for which the testimony was offered (whether the alleged infringer was a potential competitor of the patentee). *See* 105 F.Supp.2d at 700-01. Hence, the excluded expert testimony was no longer relevant to any issue in the case. Neither of these cases supports the broad, categorical exclusion of patent expert testimony that complaint counsel complaint counsel suggests.

Thus, this Court has broad discretion to accept expert patent law testimony when it is relevant and appropriate in a particular case. Here, Mr. Bjorge's testimony directly conveys evidence that was offered in the underlying *ESI* and *Upsher* cases. Mr. Miller's testimony is valuable and helpful in understanding the entirety of the evidence in the two cases. Regardless of the weight the Court ultimately accords this testimony, the Court

will likely find this testimony most helpful and appropriate in understanding the merits of the *ESI* and *Upsher* cases.

Complaint counsel's suggestion that the evaluation of patent litigation is not sufficiently reliable to be admissible under *Daubert* and *Kuhomo Tire* (Complaint counsel Br. at 15-16) requires little comment. The rule of law and the use of courts to resolve disputes are some of the great achievements of American society. We remain a government of laws, and not of men, precisely because litigation is sufficiently reliable and predictable for individuals and firms to order their affairs based on reasonable assessments of the outcome of litigation. Undoubtedly, the process of deciding litigation in accordance with the rule of law has met the standard of "general acceptance" required by *Daubert*. As Messrs. Miller and Bjorge do no more than to opine as to the outcome of litigation by applying the rule of law, their testimony is obviously appropriate under the *Daubert/Kuhomo Tire* paradigm.[10] Thus, there is no basis to exclude the testimony of Messrs. Miller and Bjorge as legal opinions.

Complaint counsel's request to limit Schering to one expert witness on the patent issues (Motion at 17-20) should also be denied. As set forth above, the testimony of these witnesses is neither overlapping nor unduly repetitive. Their testimony will differ in important respects. Dr. Banker will testify as an expert in coatings. Dr. Langer, on the other hand, will give technical testimony as to a very narrow issue relating to whether the materials in the ESI coating are mixed. Mr. Bjorge will inform the court of the patent law expert testimony he provided in the underlying cases. Finally, Mr. Miller will testify as to his review of the evidence of both parties in the case and as to the likely outcome of the two cases.

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[10] The *Independent Service Organization* case cited by complaint counsel (Br. at 16, nn. 38 & 40), does not support the assertion made by complaint counsel in its brief. The case does not even relate to a patent law expert. The expert who was excluded in that case was a technical expert who had not done sufficient work to have a legitimate basis to hold an opinion.

Complaint counsel's assertion that Messrs. Miller and Bjorge improperly incorporate the work of other experts (Br. at 19) also misses the mark. Mr. Bjorge's expert testimony is just a recapitulation of the evidence he offered in the underlying case. As such, it must be considered in the manner he offered it in the underlying cases in order to be relevant to the issues in this case.[11] Mr. Bjorge is a lawyer, and not an expert in drug coatings. To the extent his opinions incorporated underlying facts, he had no choice but to rely on other experts in his testimony in the *ESI* and *Upsher* cases. To the extent Mr. Bjorge incorporated testimony of Dr. Banker at the time, he has no choice but to do so again.

As to Mr. Miller, he reviewed the entire record and considered the testimony of all the experts, on both sides of the case. *See* Miller Ex. Rpt. ¶ 4 and Miller Tr., p. 94. To the extent he relies on testimony of Dr. Banker and Dr. Langer on a particular point, it is because he found that testimony more correct or persuasive on that point. *See, e.g.*, Miller Tr., pp. 165, 197. Hence, there is nothing improper or duplicative in his reliance on this testimony of other experts.

As noted, complaint counsel has not contested Schering's right to introduce evidence concerning the merits of the underlying patent cases. Its effort to exclude Schering's summary witness and to limit the number of expert witnesses would serve only to render this concededly relevant evidence either incomplete or difficult to follow and comprehend. The testimony of the four experts is focused, appropriate, helpful, and not unduly repetitive. Thus, none of Schering's patent experts should be excluded.

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[11] Complaint counsel's patent law experts offer flawed, improper testimony for precisely this reason. Complaint counsel's patent law experts are creating new opinions and new positions on the patent issues. *See, e.g.*, Expert Report of Professor Martin J. Adelman on Behalf of Complainant, dated November 14, 2001 ¶¶ 15 and 19 and Expert Report of Umesh V. Banakar, Ph.D. on Behalf of Complainant, dated November 15, 2001 ¶¶ 6, 7, 11-13 and 18. However, what is relevant to this case is the evidence at the time of the settlement. Hence, Schering has moved to exclude much of complaint counsel's purported expert testimony.

CONCLUSION

Schering respectfully requests that complaint counsel's Motion be denied in its entirety as to the testimony of Professor Mnookin, Mr. O'Shaughnessy, Dr. Horovitz, Mr. Furniss, Professor Willig, Dr. Addanki, and Schering's patent experts. Schering further requests that, based on its willingness to withdraw the testimony of Mr. McVey, complaint counsel's designations of portions of Mr. McVey's deposition testimony be withdrawn and prohibited from use by complaint counsel at trial.

Respectfully submitted,

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Attorneys for Respondent
Schering-Plough Corporation

Dated: January 17, 2002

CERTIFICATE OF SERVICE

I hereby certify that this 17th day of January 2002, I caused an original and one paper copy of Respondent Schering-Plough Corporation's Opposition to Complaint Counsel's Motion to Limit or Exclude Expert Witness Testimony to be filed with the Secretary of the Commission, and that two paper copies were served by hand upon:

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Erik T. Koons

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

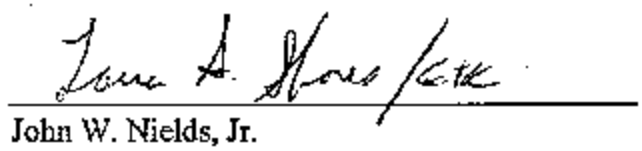
In the Matter of Schering-Plough Corporation, a corporation, Upsher-Smith Laboratories, a corporation, and American Home Products Corporation, a corporation	)	Docket No. 9297 **Public Version**

SCHERING-PLOUGH CORPORATION'S MOTION FOR THE ISSUANCE OF SUBPOENAS *AD TESTIFICANDUM*

Pursuant to Rule 3.34(a)(2) of the Commission's Rules of Practice, respondent Schering-Plough Corporation ("Schering") respectfully submits this motion for an order authorizing the issuance of 15 subpoenas *ad testificandum* to be issued to certain witnesses identified on Schering's final witness list of December 14, 2001.

The testimony of each of these witnesses is reasonably relevant to Schering's defense in this proceeding. For the reasons set forth in the accompanying memorandum, Schering respectfully requests that the Court grant its motion.

Respectfully submitted,



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Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, a corporation,	)	Docket No. 9297
and	)	**Public Version**
American Home Products Corporation, a corporation	)	

SCHERING-PLOUGH CORPORATION'S MEMORANDUM IN SUPPORT OF MOTION FOR THE ISSUANCE OF SUBPOENAS *AD TESTIFICANDUM*

Pursuant to Rule 3.34(a)(2) of the Commission's Rules of Practice, respondent Schering-Plough Corporation ("Schering") respectfully submits this memorandum in support of its motion for an order authorizing the issuance of 10 subpoenas *ad testificandum* to be issued to the following non-party witnesses identified on Schering's Final Witness List: [

] In addition, Schering requests an order authorizing the issuance of five subpoenas *ad testificandum* for the following [ ] employees identified on Schering's final witness list: [

].

Each of these individuals' testimony is reasonably relevant to Schering's defense in this matter, and thus satisfies the conditions under Rule 3.34(a)(2) for issuance of subpoenas *ad testificandum* to appear and testify at this adjudicative hearing. A brief

description of each individual's expected testimony and relevance to Schering's case follows.

Third Party Witnesses:

[ ] is an in-house attorney for [ ] Schering expects that [ ] will testify about the patent infringement suit and settlement between Schering and ESI in the case of Key Pharmaceuticals, Inc. v. ESI Lederle, Inc., Case No. 96-CV-1219 (JED) (E.D. Pa.).

[ ] is the President and Chief Executive Officer of [ ]. [ ] will testify about [ ]' development of and expectations for [ ], [ ]' sustained-release niacin product. He will also testify about [ ]' negotiations with Schering regarding [ ].

[ ] is a member of the law firm of [ ], in New York, New York. Schering expects [ ] to testify about communications between the parties during the settlement negotiations in the case of Key Pharmaceuticals, Inc. v. Upsher-Smith Laboratories, Inc., Case No. 95-CV-6281 (WHW) (D.N.J.).

[ ] was formerly the President of [ ], a business unit of [ ]. He now heads the [ ]. Schering expects [ ] to testify about ESI's operations while he was President of ESI. [ ] will also testify about ESI's development of a generic version of Schering's K-Dur 20 sustained-release potassium chloride supplement; the patent infringement suit of Key Pharmaceuticals, Inc. v. ESI Lederle, Inc., Case No. 96-CV-1219 (JED) (E.D. Pa.), filed by Key Pharmaceuticals, a division of Schering, against ESI over U.S. Patent No. 4,863,743 ("'743 patent"); settlement negotiations between Schering and ESI relating to the settlement of that suit; and about the role of federal judicial officials in those settlement negotiations. [ ] will also testify about pharmaceutical licensing agreements, including licensing of generic enalapril and buspirone to Schering, and about

ESI's generic enalapril and buspirone. [ ] will also testify about the impact of generic entrants on the price, sales and market share of a branded product.

[ ] is the [ ]. [ ] will testify about [ ] filing with FDA an ANDA for a generic 20 meq potassium chloride product and its subsequent withdrawal of that ANDA. [ ] will also testify about whether or how [ ] awareness or understanding of the settlement agreement entered into by Schering and Upsher affected [ ] plans for development or marketing of its proposed sustained-release potassium product, or the eventual withdrawal of [ ] ANDA for that product.

[ ] is a former employee of [ ]. [ ] will testify about the strength of Schering's '743 patent and ESI's efforts to develop a proposed generic version of K-Dur 20.

[ ] is [ ]. [ ] will testify about [ ]' development of and expectations for Niaspan, Kos' sustained-release niacin product. He will also testify about [ ]' negotiations with Schering regarding [ ].

[ ] is the [ ]. [ ] is expected to testify concerning deficiencies the FDA has identified in [ ] Abbreviated New Drug Application ("ANDA") for a generic 20 meq potassium chloride product. [ ] is also expected to testify that, as late as November 2001, [ ] could not market its generic potassium chloride product because it had not yet received FDA approval of its ANDA and did not know when it would receive such approval.

[ ] is the [ ]. [ ] will testify about [ ] filing with FDA of an ANDA for a

generic 20 meq potassium chloride product and the status of approval of that ANDA. [ ] will also testify whether or how [ ] awareness or understanding of the settlement agreement entered into by Schering and Upsher has affected [ ] plans for development and marketing of its proposed sustained-release potassium product.

[ ] is the [ ]. [ ] will testify about [ ] filing with FDA of an ANDA for a generic 20 meq potassium chloride product and the status of approval of that ANDA. [ ] will also testify whether or how [ ] expectations or understanding of any 180-day marketing exclusivity enjoyed by Upsher has affected [ ] plans for development and marketing of its proposed sustained-release potassium product.

[ ] Witnesses:

[ ]is [ ] for [ ]. Schering expects that [ ] will testify about [ ]'s exploration of licensing opportunities for [ ]. [ ] will also testify about [ ]'s plans for and development of [ ].

[ ] is the [ ] for [ ]. Schering expects that [ ] will testify about [ ]'s exploration of licensing opportunities for [ ], including [ ]'s negotiations with Schering for such licensing opportunities. [ ] will also testify about [ ]'s market entry plans for its proposed [ ] product.

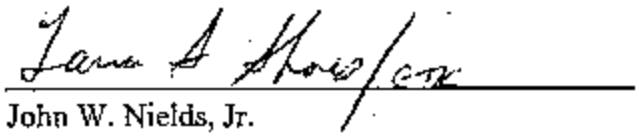
[ ] is [ ] for [ ]. Schering expects that [ ] will testify about [ ]'s exploration of licensing opportunities for [ ]. [ ] will also testify about the patent litigation between Schering and Upsher in the case of Key Pharmaceuticals, Inc. v. Upsher-Smith Laboratories, Inc., Case No. 95-CV-6281 (WHW) (D.N.J.).

[ ] is the [ ] for [ ]. Schering expects that [ ] will testify about the patent litigation between Schering and Upsher in the case of Key Pharmaceuticals, Inc. v. Upsher-Smith Laboratories, Inc., Case No. 95-CV-6281 (WHW) (D.N.J.). [ ] will also testify about [ ]'s [ ]. Schering also anticipates that [ ] will testify about [ ]'s market entry plans for its proposed [ ] product.

[ ] is the [ ] for [ ]. Schering expects that [ ] will testify about the patent litigation between Schering and Upsher in the case of Key Pharmaceuticals, Inc. v. Upsher-Smith Laboratories, Inc., Case No. 95-CV-6281 (WHW) (D.N.J.). [ ] will testify about the negotiations between Schering and Upsher over the licensing opportunities for [ ] and other products. [ ] will also testify about potassium chloride supplements currently manufactured and sold by [ ] and other pharmaceutical products that [ ] considers to compete with them.

For the foregoing reasons, Schering respectfully requests that the Court grant Schering's motion in all respects.

Respectfully submitted,



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Attorneys for Respondent
Schering-Plough Corporation

Dated: January 17, 2002

CERTIFICATE OF SERVICE

I hereby certify that this 17th day of January 2002, I caused an original and one paper copy of Respondent Schering-Plough Corporation's Memorandum in Support of Motion for the Issuance of Subpoenas Ad Testificandum to be filed with the Secretary of the Commission, and that two paper copies were served by hand upon:

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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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 SCHERING-PLOUGH CORPORATION'S MOTION FOR THE ISSUANCE OF SUBPOENAS *AD TESTIFICANDUM*

Upon consideration of Schering's Motion for the Issuance of Subpoenas Ad Testificandum, and papers relating thereto, it is IT IS HEREBY ORDERED that Schering's motion to is GRANTED, and that the Secretary shall issue to Schering subpoenas for the five individuals named in Schering's motion.

D. Michael Chappell
Administrative Law Judge

Dated: January _____, 2002

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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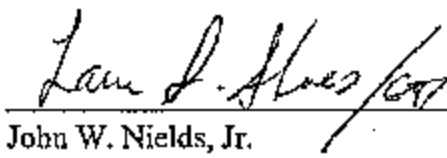
SCHERING-PLOUGH CORPORATION'S MOTION FOR THE ISSUANCE OF SUBPOENAS *AD TESTIFICANDUM*

Pursuant to Rule 3.34(a)(2) of the Commission's Rules of Practice, respondent Schering-Plough Corporation ("Schering") respectfully submits this motion for an order authorizing the issuance of five subpoenas *ad testificandum* to be issued to certain witnesses identified on Schering's final witness list of December 14, 2001.

The testimony of each of these witnesses is reasonably relevant to Schering's defense in this proceeding. For the reasons set forth in the accompanying memorandum, Schering respectfully requests that the Court grant its motion.

Respectfully submitted,



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Attorneys for Respondent
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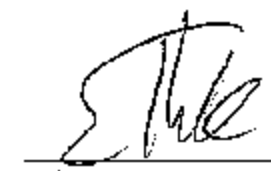

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and	)	**Public Version**
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SCHERING-PLOUGH CORPORATION'S MEMORANDUM IN SUPPORT OF MOTION FOR THE ISSUANCE OF SUBPOENAS *AD TESTIFICANDUM*

Pursuant to Rule 3.34(a)(2) of the Commission's Rules of Practice, respondent Schering-Plough Corporation ("Schering") respectfully submits this memorandum in support of its motion for an order authorizing the issuance of 5 subpoenas *ad testificandum* to be issued to the following non-party witnesses identified on Schering's Final Witness List: [

.]

Each of these individuals' testimony is reasonably relevant to Schering's defense in this matter, and thus satisfies the conditions under Rule 3.34(a)(2) for issuance of subpoenas *ad testificandum* to appear and testify at this adjudicative hearing. A brief description of each individual's expected testimony and relevance to Schering's case follows:

[ ] was, until recently, the [ ] of Schering. [ ] will testify about the June 24, 1997 meeting of Schering's board of directors at

which the Upsher licensing transaction was approved. [ ] will also testify about Schering's business and decision-making practices.

[ ] is the former [ ] Schering Primary Care business unit. Schering expects him to testify about Schering's settlement negotiations with Upsher in the case of Key Pharmaceuticals, Inc. v. Upsher-Smith Laboratories, Inc., Case No. 95-CV-6281 (WHW) (D.N.J.), and about Schering's settlement negotiations with ESI in the case of Key Pharmaceuticals, Inc. v. ESI Lederle, Inc., Case No. 96-CV-1219 (JED) (E.D. Pa.). [ ] will also testify about Schering's negotiations with Kos regarding opportunities to license Kos' Niaspan product. [ ] will also testify about K-Dur competition and Schering's business and decision-making practices.

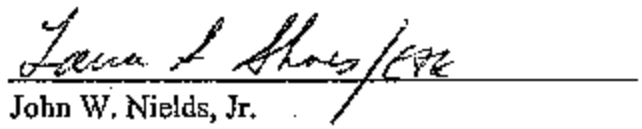
[ ] is an outside consultant who performs marketing activities for Warrick. Schering expects [ ] to testify about Warrick's efforts to market enalapril and buspirone.

[ ] currently is a partner in the [ ]. Schering expects [ ] to testify about communications between the parties during the course of settlement negotiations in the case of Key Pharmaceuticals, Inc. v. ESI Lederle, Inc., Case No. 96-CV-1219 (JED) (E.D. Pa.). [ ] is also expected to testify about communications with federal judicial officials during the course of those settlement negotiations.

[ ] is currently a partner in the [ ] Schering expects [ ] to testify about communications with federal judicial officials during the course of settlement negotiations in Key Pharmaceuticals, Inc. v. ESI-Lederle, Inc., Case No. 96-CV-1219 (JED) (E.D.Pa.).

For the foregoing reasons, Schering respectfully requests that the Court grant Schering's motion in all respects.

Respectfully submitted,



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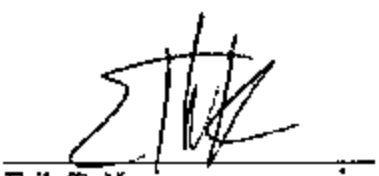

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Upon consideration of Schering's Motion for the Issuance of Subpoenas Ad Testificandum, and papers relating thereto, it is IT IS HEREBY ORDERED that Schering's motion to is GRANTED, and that the Secretary shall issue to Schering subpoenas for the 15 individuals named in Schering's motion.

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