BEFORE THE FEDERAL TRADE COMMISSION

WASHINGTON, D.C.

In the Matter of SCHERING-PLOUGH CORPORATION, UPSHER-SMITH LABORATORIES, INC., and AMERICAN HOME PRODUCTS CORPORATION	)	Docket No. 9297

APPEAL BRIEF OF RESPONDENT SCHERING-PLOUGH CORPORATION

Of Counsel:

Jonathan A. Wasserman
Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

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

Attorneys for Respondent
SCHERING-PLOUGH CORPORATION

Dated: September 30, 2002

PUBLIC VERSION

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

OTHER AUTHORITIES

TABLE OF ABBREVIATIONS

The following abbreviations and citation forms are used:

ID - Initial Decision

IDF - Initial Decision Finding of Fact

CX - Complaint Counsel exhibit

SPX - Schering-Plough exhibit

USX - Upsher-Smith exhibit

CAB - Appeal Brief of Counsel Supporting the Complaint

SPF - Respondent Schering-Plough Corporation's Proposed Findings of Fact

SR-CPF - Respondent Schering-Plough Corporation's Reply to Complaint Counsel's Proposed Findings

UPF Respondent Upsher-Smith Laboratories, Inc.'s Proposed Findings of Fact

Citations to the trial transcript include the volume and page number: (18 Tr. 4119).

Pages of exhibits are referenced by bates number: (SPX 2 at SP 16 00044).

In camera documents, testimony and findings are designated by brackets and bold text: **[SPX 2266]**.

INTRODUCTION

Settlements of patent cases in which brand name companies make net payments to generic companies raise important antitrust issues and could reach anticompetitive outcomes. But these settlements do not.

The Upsher settlement did not involve a net payment. The ESI settlement was the product of fifteen months of court-supervised mediation. And the evidence strongly suggests that the settlement brokered by Magistrate Judge Rueter was the only settlement available, and was better for consumers and competition than continued litigation.

A. The Upsher Settlement

In late 1995, Schering sued Upsher-Smith ("Upsher") for patent infringement, seeking to enjoin it from selling a generic version of K-Dur 20, Schering's sustained-release potassium chloride supplement. Had Schering prevailed, Upsher would have been enjoined from selling its product until September 2006, when Schering's patent expired. Had Upsher prevailed, it could have marketed its product sooner.

In June 1997, the parties settled by compromising Upsher's entry date. Under the settlement, Upsher could sell its generic after September 2001: five years *earlier* than if it had lost the suit, and *later* than if it had won. As part of the settlement, Schering acquired from Upsher rights to market a sustained-release niacin product called Niacor-SR, in return for $60 million in upfront royalties.

The principal issue at trial was whether Schering's acquisition of the rights to Niacor-SR for $60 million was a *bona fide* fair value transaction. Both Complaint Counsel and their economist conceded that, if it was a fair value transaction, the settlement was lawful. Thus, Complaint Counsel stated in their Trial Brief "this case does not challenge the settlement of patent disputes by an agreement on a date of entry, standing alone, *or the payment of fair market value in connection with 'side deals' to such an agreement*." (Trial Br. at 43)(emphasis added).

The overwhelming majority of the evidence submitted by all parties dealt with this fair value issue. Complaint Counsel referred to it below as "the pivotal factual dispute" in the case.[1] The Administrative Law Judge devotes 48 pages of his Initial Decision to this issue, and concluded that "[a]bundant evidence at trial established that the $60 million paid by Schering was fair value for Niacor-SR and the other licensed products." (ID 108). *But in the statement of facts in their Appeal Brief, Complaint Counsel do not mention the issue at all*. (Appeal Brief ("CAB") at 4-15).

We discuss the evidence on this pivotal issue below at pp. 7-34. The evidence includes important *contemporaneous documents*. *Contemporaneous documents* show that Schering had already evaluated another sustained-release niacin product, and concluded that its sales would likely produce revenues with a *net* present value of $254 million. *Contemporaneous documents* show that Schering evaluated Niacor-SR itself and concluded *its* sales had a *net* present value of from $225-265 million. And *contemporaneous documents* show that Schering's Board of Directors reviewed the Niacor-SR license deal separately from the settlement, and approved the Niacor-SR license only on the basis that it stood "on its own merit, independent of the settlement." (SPF 1.37, 1.48)(IDF 163).

Numerous fact and expert witnesses testified concerning the value of Niacor-SR. The witnesses included Schering officials who evaluated Niacor-SR, and licensing and scientific experts called by both sides. Judge Chappell made detailed findings concerning the fair value issue. He expressly found Schering's witnesses to be "*credible* in establishing that the licensing agreement was a *bona fide* arm's length transaction." (ID 107)(emphasis added).

In its Appeal Brief, Complaint Counsel have all but abandoned their position that the $60 million was not a fair value payment for Niacor-SR. Instead, Complaint Counsel rely on the fact that the Niacor-SR license was designed in part to address Upsher's desire for cash to replace what it had hoped to receive from sales of its generic had it won the patent case. As the

---

1 *See* Complaint Counsel's Opposition to Upsher-Smith's Motion to Exclude Rebuttal Witnesses at 7.

undisputed evidence showed, Schering's negotiators agreed to explore a side deal to address those cash needs, but only as long as the side deal "stood on its own two feet." (IDF 142, 163). The parties then negotiated the Niacor-SR license, which was made part and parcel of the settlement.

This was entirely appropriate, as Complaint Counsel's expert economist conceded at trial. Professor Bresnahan testified as follows:

> Q: Professor, isn't this like negotiations 101?
>
> A: I don't know what you mean.
>
> Q: Wouldn't any good mediator say, that's a very smart way of solving this problem? This is a very good way for the parties to try to come up with a settlement that makes sense? They pick a date that is fair, Upsher has a problem with settling on those terms because they want cash a lot now, and they're giving up the opportunity of getting it under the settlement, so the parties do a fair market value transaction that is a good deal for both parties and solves Upsher's desire for cash?
>
> A: The –
>
> Q: What's wrong with that?
>
> A: Under the assumption that it's a fair market value for both parties and under the assumption which I – which I don't know how to deal with that you defined fair ignoring the high rated discount, the – you know, if it's a – if it's a – *if they stop at a fair market value transaction, generally I don't think there's a problem*.

(6 Tr. 1219-20)(emphasis added).

Complaint Counsel failed to prove that the $60 million was anything other than a *bona fide* fair value payment for the rights to Niacor-SR. That failure is dispositive of Complaint Counsel's challenge to the Upsher settlement.

B. The ESI Settlement

In early 1996, Schering filed a patent infringement suit against ESI Lederle, Inc. ("ESI"), seeking to enjoin it from selling a generic version of K-Dur 20. If Schering had won that lawsuit, ESI could not have sold its product until September 2006, when the patent expired. If ESI won, it could have marketed its product sooner.[2]

In late 1996, the trial judge prevailed upon the parties to engage in court supervised mediation, with Magistrate Judge Rueter serving as mediator. After fifteen months of mediation, during which both the merits of the case and antitrust concerns were discussed with Judge Rueter, Judge Rueter prevailed on the parties to settle. The terms that Judge Rueter urged on the parties were as follows: ESI could sell its product any time after January 1, 2004. Schering would pay ESI five million dollars, which Judge Rueter characterized as being in the range of legal fees. And Schering would pay ESI an additional amount, up to $10 million, if ESI obtained FDA approval by 2002.

The evidence strongly suggests that Judge Rueter could not have brokered any settlement calling for entry by ESI earlier than January 1, 2004, and could not have brokered any settlement at all without at least a small payment to ESI. (IDF 356)(CAB at 14). The evidence also strongly suggests that the settlement Judge Rueter brokered was better for competition and consumers than continued litigation. Schering had a very strong patent infringement case against ESI, and was nearly certain to win. Schering's patent litigation expert so testified. Complaint Counsel hired its own patent litigation expert. But *he offered no testimony contradicting Schering's experts' evaluation of the ESI case*.

There is a strong public policy favoring settlements. Settlements permit parties to replace risk with certainty so that they can plan and allocate scarce resources in an efficient manner. And settlements are essential to the functioning of our court system. Twice in the last decade, Congress has enacted legislation enjoining federal district courts to institute formal mediation

---

[2] The Complaint alleges that ESI was, in any event, blocked from the market by Upsher's 180-day exclusivity rights, until March of 2002. See Complaint ¶¶15, 42, 66.

procedures like the one the court used in the ESI case. Notwithstanding the role the court played in the ESI settlement, Complaint Counsel introduced no evidence that *this particular settlement* reached an anticompetitive outcome. Complaint Counsel offered only the opinion testimony of its economist, Professor Timothy Bresnahan, that *all* settlements involving a net payment "deliver less competition than would litigating." (6 Tr. 1130)(SPF 3.226).

This opinion rests purely on economic theory. Professor Bresnahan has never tested it empirically.[3] (6 Tr. 1145-46)(SPF 3.220). Several reputable economists disagree with it. (6 Tr. 1131-32)(SPF 3.224). For example, Richard J. Gilbert, former Chief Economist at the Antitrust Division, expressly disagreed in an article written about this and other cases, stating "[t]he fact that the settlement involves a payment from the patentee to the challenger is *not* sufficient to determine that the settlement is anticompetitive."[4] (SPF 3.225)(SPX 836). Moreover, both Professor Bresnahan and Complaint Counsel have now conceded that when the brand name company's risk aversion is considered, Professor Bresnahan's theory does not work. *See* CAB at 68.

Complaint Counsel is thus left to argue for a *per se* or quick look rule. Adoption of such a rule in *this* case would be unwarranted. First, the effects flowing from settlements which effectively shorten the life of the brand name company's patent ("patent-shortening settlements") are inherently ambiguous. Such settlements provide for entry *earlier* than if the brand name had won the case and *later* than if the generic had won the case. The question whether a patent-shortening settlement *delays* entry and competition, as Complaint Counsel repeatedly assert, or instead *accelerates* entry and competition, depends quite obviously on who would have won the patent case. Second, this is the first case involving a patent-shortening settlement to be

---

[3] Timothy J. Muris, now Chairman of the Commission, recently warned against the "weak empirical foundation of much of modern economic theory." Timothy J. Muris, *The FTC and the Law of Monopolization*, 67 Antitrust L.J. 693, 694-95 (2000).

[4] Richard J. Gilbert and Willard K. Tom, *Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later*, 69 Antitrust L. J. 43, 78 (2001)(emphasis added). Mr. Gilbert was the principal drafter of the Intellectual Property Guidelines. *Id*.

considered by the Commission or the courts. There is simply not enough real-world experience with this type of patent-shortening settlement to support a *per se* rule.

It may be that experience will someday show that a net payment of any size in connection with a settlement creates such a high probability of an anticompetitive effect that they should be branded *per se* illegal. We doubt this in the case of patent-shortening settlements. But in no event can such a conclusion be reached in this case. Here, Complaint Counsel have not only failed to show that "all or almost all" patent-shortening settlements with payments are anticompetitive, they have failed to show that *this* settlement is anticompetitive. Before Complaint Counsel may use a litigated case as the vehicle for creating a new *per se* rule, they must at least introduce proof that *that* litigated case involved an actual anticompetitive outcome. This they have not done.

* * * * *

Trial of these cases was a substantial undertaking. Evidence was presented during 36 days of administrative hearing, over the course of 9 weeks. Thirty-six witnesses testified live, and others by deposition. 2,708 exhibits were admitted. The hearing transcript totals 8,619 pages. During the hearing, Complaint Counsel tried to paint Schering as a company eager to pay its generic rivals to stay off the market, and willing to use side transactions as a "veil" or "disguise" for doing so. But the evidence presented at trial did not show that at all. And the Administrative Law Judge, who heard the testimony of the Schering witnesses live and found them to be credible, found the side transactions to be fair value deals entered into in good faith.

There are a number of settlements of patent suits involving net payments described in a recent Commission report, which may *not* be ambiguous in their effects on competition and consumer welfare because they do not involve any patent shortening. *See Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002). These are settlements in which the entry date was *not* compromised, and in which the generic agreed to stay off the market until patent expiration. And some may involve drugs with monopoly power. But neither the Upsher settlement nor the ESI settlement is such a case.

I. THE UPSHER SETTLEMENT

FACTS

A. Complaint Counsel Concede that Payment of Fair Value in a Side Deal Done in Connection with a Settlement is Permissible

Complaint Counsel and their expert economist, Professor Bresnahan, agree that there is nothing wrong with paying fair value for licensing rights in a side deal done in connection with a settlement. Complaint Counsel said precisely that in their trial brief: "This case does not challenge the settlement of patent disputes by an agreement on a date of entry, standing alone, *or the payment of fair market value in connection with 'side deals' to such an agreement.*" (Trial Br. at 43)(emphasis added). Professor Bresnahan admitted the same thing. When asked what was wrong with a settlement that solved Upsher's need for cash through a side deal done for fair value, Professor Bresnahan replied:

> Under the assumption that it's a fair market value for both parties and under the assumption which I—which I don't know how to deal with that you defined fair ignoring the high rated discount, then you know, if it's a—if it's a—*if they stop at a fair market value transaction, generally I don't think there's a problem*.

(6 Tr. 1220)(emphasis added)(SPF 3.370-3.375). He concluded that "if Schering-Plough had made a stand-alone determination that it was getting as much in return from those products as it was paying, then I would infer they were not paying for delay." (5 Tr. 964-65)(IDF 172). Judge Chappell appropriately found that Complaint Counsel's expert had conceded that a side deal done for fair value did not raise competitive concerns. (IDF 172).

B. Complaint Counsel Failed to Prove that the Side Deal Was Not Done for Fair Value

Complaint Counsel's case that Schering had paid Upsher more than fair value was presented through Professor Bresnahan, an economist, and Dr. Levy, a licensing expert. Complaint Counsel called no live fact witnesses on the fair value issue. The testimony of Professor Bresnahan and Dr. Levy fell short. We will discuss the testimony of these two experts below.

1. Professor Bresnahan's Testimony

Professor Bresnahan gave four bases for his opinion that the $60 million was not a *bona fide* fair value payment for Niacor-SR.

a. Incentives

First, Professor Bresnahan argued that Schering had an incentive to pay Upsher to delay marketing its generic version of K-Dur 20, and therefore must have done so. (3 Tr. 512-40). But Professor Bresnahan conceded that the existence of an economic incentive to violate the law is not proof that someone has violated the law. (9 Tr. 1105). He said, quite correctly, that most people, including businessmen at large companies, obey the law regardless of their economic incentives. (9 Tr. 1107-08).

Antitrust courts have taken a similar view. *See Serfecz v. Jewel Food Stores*, 67 F.3d 591, 600-01 (7th Cir. 1995) ("[P]roof of motive is of limited utility in this context. Although a lack of motive may be evidence that parties did not conspire, the presence of an economic motive is of very little probative value. . . . The mere confluence of economic interests between the parties does not establish, standing alone, the existence of a conspiracy"); *In re Baby Food Antitrust Litig.*, 166 F.3d 112, 134 (3d Cir. 1999) (dismissing opinion of plaintiff's economist as "nothing more than an abstract statement based on 'economic theory' that the interest in enhancing profits motivated the defendants to conspire"). Judge Chappell was correct in concluding that theoretical economic incentives do not constitute proof of improper conduct. (ID 110).

b. Deposition testimony of witnesses who negotiated the settlement

Professor Bresnahan also purported to rely on deposition testimony of the fact witnesses who participated in the settlement negotiations. (6 Tr. 1092). He characterized this testimony as "direct evidence" that Schering agreed to purchase delay from Upsher. (*Id*.) But at the hearing,

Professor Bresnahan conceded that each witness actually testified that Schering *refused* to pay Upsher to stay off the market:

> Q. And in fact, in your report, you have a separate section headed Direct Evidence in which you conclude that there is direct evidence that Schering purchased delay from Upsher, and then you proceed to discuss the deposition testimony of the participants in the negotiation.
>
> Do you recall that?
>
> A. I do.
>
> Q. And the testimony you discuss is testimony from Mr. Hoffman, Mr. Driscoll, Mr. Troup and Mr. Kapur. Do you recall that?
>
> A. I think that's right, yes.
>
> Q. Isn't it true, Professor, that each one of these people testified that Schering *refused* to pay Upsher to stay off the market?
>
> A. Yes, that's right.

(6 Tr. 1092-93)(emphasis added)(SPF 1.41).

Professor Bresnahan's concession on cross-examination was compelled by the evidence. (*See* ID 110). Mr. Hoffman, Schering's in-house antitrust counsel, had testified as follows when asked about discussions of payment for delay: "I don't recall whether that was asked for directly. I recall it was my sense that that was something [Upsher] thought we should do. And I recall telling them *we were not going to do that*." (CX 1508 at 35)(emphasis added)(SPF 1.44). Mr. Hoffman had also testified in his deposition that he told Mr. Cannella, Upsher-Smith's outside counsel, that "we were not going to pay Upsher to stay off the market, nor did I think that subject should be discussed." (SPX 1240 at 32)(SPF 1.44)(IDF 139).

Mr. Driscoll, who was Vice President for Key Pharmaceuticals, Inc. ("Key") and the principal negotiator for Schering in early discussions about settlement, had testified that when Upsher raised the subject of a payment to stay off the market, he made it clear Schering would

not do that. He had testified: "I indicated very forcefully that Schering was not going to pay any sum to Upsher-Smith simply for them to stay off the market"; "I was very forceful in saying, we simply cannot do that." (CX 1494 at 66)(SPF 1.42).

Mr. Kapur, who was present at one of the meetings attended by Mr. Driscoll and Mr. Troup, confirmed Mr. Driscoll's recollection. He had testified in deposition that Mr. Driscoll "was very clear that, you know, his attorneys would not allow him to make any financial settlement and, therefore, he was not willing to—he ruled out making any payment to Upsher-Smith." (SPX 1242 at 21)(SPF 1.43). Mr. Kapur had given similar testimony in his investigational hearing:

> Q. Did Mr. Driscoll say why he would not pay Mr. Troupe [sic]?
>
> A. He said as—my recollection is he told him that his legal people . . . [t]hat his legal people would not allow him to do that.

(SPX 1241 at 49-50)(colloquy omitted)(SPF 1.43).

What the direct evidence showed is that a payment for delay was proposed by Upsher-Smith but rejected by Schering. (SPF 1.13, 1.41-1.49)(IDF 139, 141, 142). This falls woefully short of proving the existence of a conspiracy. *See In re Citric Acid Litig.*, 191 F.3d 1090, 1098 (9th Cir. 1999)("It would not be reasonable to infer that Cargill engaged in illegal activities merely from evidence that an illegal course of action was suggested but immediately rejected"), *cert. denied*, 529 U.S. 1037 (2000).

The evidence shows further that the parties had then discussed a settlement around the concept of compromising Upsher's entry date. (SPF 1.9, 1.11). The date tentatively agreed on was September 1, 2001. Upsher expressed concern about its need for cash between the date of settlement and the September 2001 date of entry. (IDF 141). The parties thus explored other business transactions as a way of satisfying Upsher-Smith's desire for cash before 2001. (CX 1508 at 36)(SPF 1.10, 1.15, 1.19, 1.47)(IDF 142-146). Mr. Hoffman told Mr. Troup that such a transaction would be acceptable "as long as that deal stood on its own two feet." (CX 1508 at 36)(SPF 1.47)(IDF 142). Mr. Hoffman explained that any side transaction would have to be "a

separately valued deal that we would do, with or without the settlement." (SPX 1239 at 37)(SPF 1.47).[5]

Mr. Hoffman, thus, suggested an approach to settlement that matches precisely the position taken by Complaint Counsel in their Trial Brief: a settlement which splits the remaining patent life, and includes a side transaction for fair value.

c. The "Revealed Preference" Test

Professor Bresnahan testified that Schering's decision not to pay a company called Kos for the right to co-promote a sustained-release niacin product called Niaspan "revealed a preference" not to pay anyone $60 million to license a sustained-release niacin product. (4 Tr. 582)(SPF 1.386). Professor Bresnahan's "revealed preference" test revealed nothing of the sort. Instead, Schering's negotiations with Kos support Schering's position in this case. Those negotiations reveal that (1) Schering was interested in sustained-release niacin products prior to and wholly independent of any settlement discussion with Upsher, and (2) that Schering believed a sustained-release niacin product would garner significant sales in the marketplace. (SPF 1.387). The evidence also shows (3) that Schering's decision to discontinue discussions with Kos was made for reasons that did not apply to its transaction with Upsher. (SPF 1.388).

---

[5] This is precisely the search for value-creating trades that Schering's negotiating experts, Professor Mnookin and Mr. O'Shaughnessy, explained was so beneficial to the dispute resolution process. Professor Mnookin, who is in charge of Harvard's Project on Negotiation explained that "it is important as part of the process for parties to search for opportunities unrelated to the dispute itself, where they can engineer new transactions, make deals of various sorts," because "if they can create value through an unrelated transaction, that value will often make it possible for them each to end up concluding that on balance, they're better off settling where the settlement includes" an unrelated side transaction. (12 Tr. 2678)(SPF 3.370). Professor Mnookin testified that this is one of the core themes of his teaching, (*id*.); and Mr. O'Shaughnessy, an experienced mediator, testified that extrinsic value creation has been essential to achieving settlements in at least half of the cases in which he has been involved. (29 Tr. 7082-83)(SPF 3.371-3.372, 3.374). Complaint Counsel's negotiation expert, Professor Bazerman, who also works in Harvard's Project on Negotiation, agreed that settlement is promoted when parties can find value-creating trades outside the immediate scope of the original dispute. (36 Tr. 8603)(SPF 3.374).

(1) Schering's Interest in Sustained-Release Niacin

Kos had a sustained-release niacin product in development called Niaspan. In early 1997, Schering approached Kos to discuss a possible *co-promotion* arrangement for Niaspan whereby Schering would contribute its sales force and the two companies would share the profits. (SPF 1.84, 1.86, 1.91-1.92)(IDF 201-205). Quite obviously, Schering's interest in Niaspan had nothing to do with settlement of any patent suit. Schering had no litigation of any kind pending with Kos.

Schering believed that a sustained-release niacin product had significant market potential. (SPF 1.85)(IDF 201). In addition, Schering very much wanted to develop expertise selling a cholesterol drug before launching its blockbuster cholesterol-reducing pipeline drug, ezetimibe. (15 Tr. 3437-38; 18 Tr. 4108-09)(SPF 1.86, 1.88, 1.223)(IDF 202). This strategic reason for Schering's interest in Niaspan was recorded in contemporaneous documents, and corroborated by witnesses. (CX 546 at SP 002770)(SPF 1.222-1.223). In fact, Complaint Counsel's rebuttal witness from Kos, Mr. Patel, testified that Schering representatives explained to him that this strategic fit with ezetemibe "was *the very reason* [Schering] wanted to talk to" Kos about Niaspan. (31 Tr. 7546-47)(SPF 1.223).

Schering put substantial effort into analyzing the market opportunities for Niaspan. (*See* IDF 211). In April 1997, Schering engaged an outside firm to perform market research to determine physicians' reactions to a sustained-release niacin product. (CX 576)(SPF 1.104-1.106). Schering sought input from at least twelve foreign subsidiaries to determine their interest in sustained-release niacin. (CX 544)(SFP 1.103, 1.228). And Schering studied significant quantities of information about Niaspan itself. (15 Tr. 3441)(31 Tr. 7544)(SPF 1.84, 1.89).

Ray Russo, Schering's marketing director for cardiovascular products and three others from Schering traveled to Kos' headquarters in Miami to discuss a possible deal. (15 Tr. 3433-34: 3449-52)(CX 1047)(31 Tr. 7545)(SPF 1.87, 1.108). Some potentially problematic issues, resulting from the fact that the deal under discussion was a *co-promotion*, emerged by the end of

the meeting. Under a co-promotion, unlike a *license*, the two parties would share both profits and control. Kos wanted Schering to commit to a significant amount of "primary" detailing – *i.e.,* to commit to favor Niaspan over Schering's other drugs in sales calls to physicians. (SPF 1.116)(IDF 207). Each company wanted to "book" sales, so that the Niaspan sales would show up on its financial records as sales of that company. (SPF 1.119)(IDF 207). And each company wanted strategic control of major marketing decisions. (SPF 1.118)(IDF 207). Nonetheless, Schering remained interested in the product.

(2) The Value Schering Placed on Niaspan

The market was projecting significant sales in the United States for Niaspan. In March 1997, in an initial public offering, Kos raised over $62 million by selling 29 percent of its stock to the public. (USX 21)(SPF 1.81). Immediately after the IPO, the market capitalization of Kos, which was based primarily on the promise of Niaspan, was approximately $200 million. (SPF 1.81-1.82).

Schering made written sales projections for Niaspan which were more modest than the stock analysts'; but they were substantial nonetheless. (SPF 1.126, 1.132)(IDF 257). Mr. Russo projected U.S. sales for Niaspan in a contemporaneous document. Schering projected sales exceeding $100 million in the third year and rising higher in later years:

Sales ($)	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Millions	**7.022**	**48.247**	**101.659**	**106.941**	**126.872**	**133.662**	**140.816**	**152.989**	**174.128**

(SPX 45)(SPF 1.126). Schering also performed a net present value analysis for Niaspan. (CX 551)(SPF 1.129-1.130). Schering estimated that the anticipated profits from Niaspan sales in the United States had a net present value of $254 million. (SPX 47)(SPF 1.131). There is no suggestion that these sales projections for Niaspan represent anything other than Mr. Russo's best business judgment at the time. (6 Tr. 1114)(SPF 1.127-1.128).

(3) Schering's Reasons for Ending Negotiations with Kos

Schering proceeded to make a written proposal to Kos. (SPF 1.142)(IDF 214). Schering proposed [**XX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXX**]; CX 554)(SPF 1.144). [**XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXX**]; SPX 619 at SP 002726)(SPF 1.144). [XXXXXXXX **XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXX**]; SPX 619 at SP 002724, 2726)(SPF 1.144). Finally, Schering suggested a 50/50 profit split and that Schering book sales. (SPX 619)(SPF 1.145-1.146)(IDF 215).

Kos' reaction to Schering's proposal was disquieting. Dan Bell, Kos' president, told Mr. Russo he was "downright *offended*." (SPX 230)(SPF 1.149)(IDF 217). He "proceeded to give Ray [Russo] a very hard time; saying that our position was practically *insulting*." (SPX 230 at SP 002721)(emphasis added)(SPF 1.149)(IDF 217). [**XXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX]** (31 Tr. 7531-32, [XXXXXXXXX**]**; CX 769)(SPF 1.150)(IDF 218). Kos wanted a higher level of promotion and field force activity than Schering was offering to commit. (SPF 1.151)(IDF 218). Kos wanted to retain marketing control of Niaspan. (SPF 1.152)(IDF 218). Mr. Bell told Schering that **[XXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXX]**. (31 Tr. 7567, **[XXXXXXXXXX]**)(SPF 1.152)(IDF 218). And in response to Schering's proposal that Schering book sales, [XXXXXXXXXXXXXX **XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX])(**SPF 1.153). Kos never made a counterproposal and negotiations broke down. (31 Tr. 7568)(SPF 1.155)(IDF 218).

Schering's reasons for discontinuing the Niaspan negotiations related to factors not present in the Niacor-SR license transaction. (SPF 1.393). First, the Kos negotiations involved a possible *co-promotion* arrangement. Schering was to receive *at most* half the profits from Niaspan sales. This meant that, as is reflected in a contemporaneous document, the projected net

present value of *Schering's* interest in Niaspan profits was, at most, $127 million. (CX 558; 25 Tr. 3529-30)(SPF 1.390). By contrast, the Upsher negotiations involved an exclusive *license.* Schering was to receive all of the Niacor-SR sales after deducting royalty payments. (SPF 1.390) The projected net present value of Schering's interest in the Niacor-SR sales was $225-265 million. (SPF 1.390)(IDF 259).

Second, Kos wanted to retain most of the control over how the product was marketed. (6 Tr. 1112)(SPF 1.118, 1.152, 1.392)(IDF 218). Third, Kos insisted on booking sales or making Schering pay to book sales. (31 Tr. 7556)(SPF 1.392)(IDF 218). And fourth, and very importantly, the Kos people were proving to be very difficult to work with. (6 Tr. 1122-24)(SPF 1.157, 1.392)(IDF 219). They treated Schering representatives with "great disrespect." (7 Tr. 1411). This did not bode well for a potential partnership, and was an important factor in Schering's decision to terminate discussions. (SPF 1.392).

The "preferences" that emerge from Professor Bresnahan's "revealed preference" test are Schering's preference not to enter into a co-marketing arrangement with a difficult partner, a preference for an arrangement under which it could keep almost all of the profits over one under which it could keep less than half, and a preference to retain control over the priorities of its own sales force. Judge Chappell's determination that "the substantial, reliable evidence demonstrates legitimate, credible reasons for Schering's preference of a licensing deal with Upsher-Smith over a co-marketing arrangement with Kos," (ID at 110)(citing IDF 217-19), is thus supported by the record evidence.

d. The "Market Test"

Finally, Professor Bresnahan relied on something he called his "market" test. He testified that because no other company had yet offered Upsher-Smith a substantial noncontingent payment for Niacor-SR, the "market test of the $60 million payment is failed." (4 Tr. 601-02)(SPF 1.396).

Professor Bresnahan's market test turned out to be of no use. First of all, several other companies *had* expressed interest in Niacor-SR and had simply not completed their evaluation of Niacor-SR when Upsher did the deal with Schering. (ID 110)(SPF 1.401-402). Second, the "market test" did not fit the way Schering and other pharmaceutical companies normally go about deciding what to pay for a license. (6 Tr. 1125)(SPF 1.396-1.397).

As Schering executive Thomas Lauda explained, there is no "market price" for a licensing opportunity. (SPF 1.397)(IDF 324). Schering generally does not know what other companies are bidding, and Schering's determination of its bid is driven instead by the company's own internal assessments. (19 Tr. 4374-75)(SPF 1.397)(IDF 324). Complaint Counsel's rebuttal witness, Mr. Egan, confirmed that one company may value a licensing opportunity differently from another. (33 Tr. 7964)(SPF 1.399)(IDF 324). It is not uncommon in the industry for several companies to decline a licensing opportunity that develops into a successful product for another company. (33 Tr. 7965)(SPF 1.399).

Moreover, Professor Bresnahan ignored the one real-world market that sometimes *does* place a measurable value on a pharmaceutical product in development: the stock market. By mid-1997, Kos had a market capitalization of over $500 million, based primarily on the promise of Kos' only real product, Niaspan. (SPF 1.400). Professor Bresnahan conceded that under those circumstances, the stock market valued Niaspan at somewhere in the range of $500 million. (6 Tr. 1129)(SPF 1.400).

Thus, at the time Schering entered into the agreement with Upsher-Smith, the "market" valued a comparable sustained-release niacin product at $500 million. (SPF 1.400). Professor Bresnahan was therefore unable to persuade Judge Chappell that his "market test" demonstrated that Niacor-SR was not worth what Schering paid for it. (*See* ID 110)(IDF 323-26).

2. Dr. Levy's Testimony

The only other evidence introduced by Complaint Counsel on the fair value issue was the opinion testimony of Dr. Nelson Levy. Since Dr. Levy's testimony was a frontal assault on the

credibility of Schering's evaluation of Niacor-SR, we will first describe the evaluation Dr. Levy attempted to challenge.

a. Schering's Evaluation of Niacor-SR

After Schering made clear to Upsher that it would consider licensing Upsher products, but only if the license stood on its own merit, Upsher offered Schering an exclusive license to market Niacor-SR outside the United States, Canada and Mexico. (SPF 1.16-1.17).[6] Mr. Kapur and Mr. Driscoll presented the Niacor-SR license opportunity to Mr. Cesan, Schering's president of pharmaceuticals worldwide. (CX 1510 at 66:18-67:4; SPX 1242 at 29:16-30:15; CX 1511 at 23-25)(SPF 1.19). Mr. Cesan directed Mr. Kapur to contact Thomas Lauda, Schering's Executive Vice President in charge of Global Marketing, to see if he would be interested in marketing Niacor-SR internationally; and stated that if Global Marketing had no interest, then Schering should decline the opportunity. (CX 1510 at 67:23-68:20; SPX 1242 at 31:8-20; CX 1489 at 14:18-25)(SPF 1.19).

Mr. Lauda received a data package on Niacor-SR, including clinical trial results which Upsher had provided. He asked James Audibert to evaluate the licensing opportunity.

(1) Mr. Audibert's Qualifications

Mr. Audibert was extraordinarily well qualified for the task. Mr. Audibert had a master's degree in pharmacology (SPF 1.197)(IDF 229), and a strong background in both science and marketing. He had extensive research and development and clinical trial experience. **(**SPF 1.198-203**)**. He had designed, reviewed, and evaluated numerous clinical trials. (SPF 1.199, 1.201**)**. He had extensive experience with sustained-release drug delivery systems. (SPF 1.198-1.203)(17 Tr. 4088-89). He was extremely knowledgeable about cholesterol drugs and the cholesterol market generally, and about niacin in particular. (18 Tr. 4097-99)(SPF 1.209,

---

[6] Upsher also offered, and Schering took, licenses on three other products. They were of course worth something to Schering. (SPX 128). However, most of the value to Schering came from Niacor, (8 Tr. 1615-16, 1638-39), and we will hereafter refer to all of the licenses as "the Niacor-SR license."

1.216)(IDF 232, 233, 237). And he was also experienced in the marketing and pricing of pharmaceutical products in Europe and other overseas markets. (SPF 1.201, 1.204, 1.205). Dr. Levy, who took it upon himself to criticize Mr. Audibert's evaluation of Niacor-SR, lacks almost all of these qualifications.

Mr. Audibert was a practicing pharmacologist in the early 1970's. (SPF 1.197). He worked for two pharmaceutical companies, Dooner Labs and Key Pharmaceuticals ("Key") from 1976 to 1986. In 1986, Schering acquired Key, and Mr. Audibert has worked for Schering ever since. (SPF 1.198, 1.200). From 1976 to 1995, Mr. Audibert held positions in research and development, sales and marketing at these three companies. (SPF 1.199-1.205).

In 1995, Mr. Audibert joined Global Marketing at Schering. (SPF 1.205) Within Global Marketing, he headed the cardiovascular and central nervous system ("CNS") business unit. (SPF 1.205). Mr. Audibert's responsibilities included ezetimibe, the potential $6 or $7 billion a year blockbuster cholesterol drug Schering had in development. (18 Tr. at 4093)(SPF 1.205-1.206).

By early 1997, Mr. Audibert was spending 35% to 40% of his time working on ezetimibe. (SPF 1.207). Mr. Audibert had conducted a detailed evaluation of the market for cholesterol-lowering drugs. (SPF 1.207, 1.208). Mr. Audibert (1) reviewed secondary information, including published literature, regarding the market and products within it; (2) conducted primary market research around the world, including interviewing physicians on what they perceived to be unmet needs and future trends in cholesterol management; (3) convened advisory panels to obtain input from experts in the cholesterol-lowering field; (4) attended major cardiology meetings around the world dealing with cholesterol management and the development of future cholesterol-lowering products; and (5) traveled to Schering's subsidiaries around the world to meet with experts and local opinion leaders in cholesterol management. (18 Tr. 4095-96)(SPF 1.208)(IDF 232).

Mr. Audibert studied the major cholesterol-lowering products on the market in 1997, including statins, fibrates, resins, and niacin. (*Id.* at 4097-98)(SPF 1.209). He was fully aware

of available scientific knowledge regarding niacin, including: the fact that niacin had been known for many years to have a positive effect on *all* of the lipid parameters that are important in cholesterol management; and the fact that niacin has been shown to be effective in long-term morbidity studies. (SPF 1.216). Mr. Audibert also knew that the NIH-sponsored National Cholesterol Education Program ("NCEP") treatment guidelines recommended niacin as one of the agents for use in managing cholesterol. (18 Tr. 4099-4100)(SPF 1.216)(IDF 237).

However, Mr. Audibert was also acutely aware of the fact that immediate-release forms of niacin were limited by the side effect of flushing, a non-dangerous but annoying side effect that severely reduced patient compliance; and that sustained-release niacin dietary supplements had been associated with substantial elevations in liver enzyme levels. (SPF 1.216).

(2) Involvement in the Evaluation of Kos' Sustained-Release Niacin in Spring 1997

In the spring of 1997, Mr. Audibert participated in Schering's evaluation of the opportunity to co-promote Kos' Niaspan. (18 Tr. 4092, 4100-02)(SPF 1.217)(IDF 239-42). Niaspan was a sustained-release niacin product. The concept behind the sustained-release formulation was to provide the known cholesterol-reducing benefits of niacin in a formulation that reduced the side effect of flushing.

During his involvement in the Kos negotiations, Mr. Audibert learned that Niaspan had achieved a low incidence of both flushing and elevated liver enzymes. He also learned that Kos had applied for FDA approval, and that the FDA had completed its medical review of Niaspan and was discussing labeling with Kos. (18 Tr. 4105; SPX 18 at SP 002776)(SPF 1.226)(IDF 240). Because the FDA does not address labeling until it has determined a product is safe and effective, FDA's completion of its medical review and focus on labeling indicated to Mr. Audibert that the FDA had concluded that Niaspan's sustained-release formulation was indeed safe and effective. (18 Tr. 4101-02, 4105-06)(SPF 1.226)(IDF 241).

(3) Mr. Audibert's Evaluation of Niacor-SR

Mr. Audibert's review of Niacor-SR began when he received the Niacor-SR data package that Upsher had given Schering. (SPF 1.232)(IDF 243-247). The package included results from the two pivotal clinical trials conducted by Upsher to obtain approval of Niacor-SR. (CX 1042)(SPF 1.232)(IDF 243).

Mr. Audibert's evaluation of Niacor-SR was consistent with his usual approach in assessing licensing opportunities. (18 Tr. 4115)(SPF 1.233). First, it was Mr. Audibert's practice to educate himself about the particular therapeutic area in which the product would compete. (SPF 1.234)(IDF 231-233). In this case, Mr. Audibert was already intimately familiar with the cholesterol-lowering market as a result of his work on ezetimibe. (18 Tr. 4094-98, 4115-16)(SPF 1.234)(IDF 237).

Second, it was his practice to determine whether there existed "proof of principle," evidencing the successful use of this type of drug in the treatment of the conditions for which the product was intended. (18 Tr. 4116)(SPF 1.235). Mr. Audibert already knew that niacin was effective in the treatment of various lipid parameters and had been incorporated into NCEP treatment guidelines. (SPF 1.235)(IDF 237). He also knew from his discussions with Kos that the FDA was close to approving Niaspan for the exact same indication that Niacor-SR was pursuing. (18 Tr. 4101-05, 4116; 11 Tr. 2454)(SPF 1.235).

Third, it was Mr. Audibert's practice to determine whether the product under consideration would satisfy *an unmet need* in the relevant therapeutic area. (SPF 1.236)(IDF 232). Mr. Audibert concluded that a sustained-release niacin product that minimized the flushing associated with immediate-release formulations without causing the high incidence of liver enzyme elevations associated with prior sustained-release formulations would satisfy such an unmet need. (18 Tr. 4116-17)(SPF 1.236)(IDF 245-247).

Mr. Audibert's conclusion in this regard was confirmed at the hearing by Schering's licensing expert, Dr. Horovitz, who testified that in his opinion a market opportunity existed in

June 1997 for a sustained-release niacin product as both monotherapy and combination therapy. (16 Tr. 3621-22, 3639-40)(SPF 1.236).

(4) The Data Package

Having identified an unmet need in the market, Mr. Audibert conducted an evaluation of Niacor-SR to determine whether it satisfied that market opportunity. (SPF 1.237)(IDF 243). The 52-page data package provided by Upsher to Schering contained highly detailed summaries of the results of Niacor-SR's phase III pivotal trials. (*Id.*).

(a) Efficacy

The clinical data from Upsher's pivotal trials confirmed to Mr. Audibert that Niacor-SR was effective: it exceeded the regulatory hurdle of an average 15% reduction in LDL cholesterol at both the 1500 mg and 2000 mg daily dosage levels. (CX 1042)(SPF 1.242)(IDF 244). In addition, Niacor-SR was also effective in raising HDL, lowering triglycerides and reducing Lp(a). (SPF 1.242).

(b) Flushing

The clinical data from Upsher's pivotal trials demonstrated to Mr. Audibert that Niacor-SR had reduced the incidence of flushing to one-fourth of that caused by immediate-release niacin. (SPF 1.244)(IDF 245). Dr. Horovitz reached a similar conclusion. (SPF 1.244).

(c) Liver Enzyme Elevations

The clinical data from Upsher's pivotal trials showed Mr. Audibert that Niacor-SR caused a low incidence of liver enzyme elevations. (SPF 1.245)(IDF 246). In evaluating this information, Mr. Audibert focused on the percentage of patients who experienced successive liver enzyme elevations above *three times the upper limit of normal*, which is the criterion that clinicians and regulators use to evaluate all cholesterol drugs. (SPF 1.245).

The Niacor-SR pivotal trials revealed that only 4% of patients taking the highest doses of Niacor-SR experienced successive liver enzyme elevations above three times the upper limit of

normal. (CX 1042 at SP 16 00092)(SPF 1.246). Mr. Audibert noted that the incidence of liver enzyme elevations in Niacor-SR pivotal trials was consistent with that seen in cholesterol-lowering drugs generally, and was *substantially* lower than the 66% incidence associated with prior sustained-release niacins. (18 Tr. 4104-05, 4120-21, 4124)(SPF 1.246)(IDF 246).

The results of the Niacor-SR pivotal trials also revealed that the liver enzyme elevations returned to normal when the drug was discontinued. (CX 1042 at SP 16 00093)(SPF 1.247)(IDF 246). Reversibility was important to Mr. Audibert, because it meant that, as is the case with the elevations associated with all cholesterol drugs, physicians could manage patients' therapy through periodic monitoring of liver enzymes. (SPF 1.247).

Dr. Horovitz, Schering's licensing expert, agreed with Mr. Audibert's conclusions regarding the liver enzyme elevations. He explained that they were in the same "ballpark" as those seen with other highly successful cholesterol drugs. (16 Tr. 3651)(SPF 1.248). For example, the market dominating statins are associated with successive liver enzyme elevations of three times the upper limit of normal in as many as 5% of patients. (16 Tr. 3651; 9 Tr. 1812-13; SPX 1209)(SPF 1.248).

(5) Mr. Audibert's Sales and Profit Projections

Having determined that Niacor-SR's product profile was safe and effective and satisfied an unmet need in the marketplace, Mr. Audibert proceeded to construct a sales forecast. (SPF 1.275).

Mr. Audibert concluded that the cholesterol market in the relevant geographic area outside the United States was $4 billion in 1997 and would likely grow to $12 billion by 2006. (SPX 2 at SP1600046). His conclusions are reflected in and supported by contemporaneous documents. (SPX 2; SPX 5; SPF 1.60, 1.278).

Mr. Audibert projected that Niacor-SR would obtain an initial market share of just .75%, rising for just two years to 1.5%, and then decreasing thereafter to 1%. (SPF 1.282)(IDF 250).

Dr. Horovitz testified that, in his opinion, these market share projections were "very small and reasonable." (16 Tr. 3674-75)(SPX 1.282).

Having estimated the size of the market and a market share for Niacor-SR over a ten-year period, arriving at the sales forecasts was largely a matter of multiplication. (18 Tr. 4127)(SPF 1.283)(IDF 251). Mr. Audibert's contemporaneous written assessment of Niacor-SR, dated June 17, 1997, includes tables illustrating his projections of market size and market share, from which he calculated dollar sales. (SPX 2 at SP 16 00046-47)(SPX 1.283). The sales projected for each of these years, in millions, were as follows:

Sales ($)	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**
Millions	45	70	114	126	116	127	140	125	136	149

(SPX 2 at SP1600047)(SPF 1.283). Mr. Audibert's projections are comparable to Mr. Russo's Niaspan projections for the similarly sized (SPF 1.60) United States market:

Sales ($) (millions)	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Niaspan	7	48	101	106	126	133	140	152	174

(SPF 1.315-1.317).

On the basis of his sales projections, Mr. Audibert prepared a profit and loss analysis. (SPX 6)(SPF 1.284). The annual profit and loss calculations were created by deducting from his sales forecasts an estimated 10% cost of goods, as well as the cost of selling and promoting Niacor-SR, which Mr. Audibert estimated to peak at $22.8 million in the third year. (SPX 6)(SPF. 1.284)(IDF 252). Because Mr. Audibert did not know what royalty rate would be negotiated, his calculations represented the annual net profit before deducting royalties to be paid to Upsher-Smith. (18 Tr. 4139)(SPF 1.284)(IDF 252).[7]

---

[7] Mr. Audibert's contemporaneous written assessment contains a number of assumptions upon which his sales projections were based. (18 Tr. 4129-37; SPX 2)(SPF 1.287). Dr. Horovitz, who conducted a detailed evaluation of

Mr. Audibert, who was not aware of the patent litigation, testified that the sales projections represented his best business judgment regarding what Niacor-SR would bring in the overseas market. (18 Tr. 4225-26)(SPF 1.286, 1.305).

(6) The License is Negotiated

Mr. Audibert's sales projections were used by Mr. Lauda in concluding that the Niacor-SR licensing opportunity was worth more than $60 million to Schering. (SPF 1.328, 1.330)(IDF 258). The negotiators then negotiated a license deal with Upsher calling for $60 million in upfront royalty fees, $10 million in milestone royalty payments, and running royalties on sales of 10% or 15% depending on the level of sales. (SPF 1.27, 1.29)(IDF 153).

Schering's corporate finance department plugged the royalties into Mr. Audibert's sales projections and calculated that Niacor's projected sales, after deducting the royalty payments due Upsher, had a net present value to Schering of from $225 to $265 million. (SPF 1.328)(IDF 259).

(7) Board of Directors Approval

The licensing transaction was not a contract until it had been ratified by Schering's Board of Directors. (CX 347 at SP 12 00190)(SPF 1.48)(IDF 163). The Board presentation memorandum explained that Schering negotiators had been informed in the settlement negotiations that Upsher was seeking cash to replace what it might have received prior to September 2001 from sales of its potassium chloride product had it been successful in the litigation. (CX 338 at SP 12 00268)(SPF 1.37)(IDF 163). The memorandum also advised the Board that the license opportunity could only be approved if it was of sufficient value to Schering, separate and apart from the settlement agreement. (SPF 1.37, 1.48). Thus, the Board was advised that "any such deal should stand *on its own merit independent of the settlement*." (CX 338 at SP 12 00268)(emphasis added)(SPF 1.37). Hans Becherer, one of Schering's

---

Mr. Audibert's assumptions, concluded that each was reasonable and conservative. (16 Tr. 3612, 3675)(SPF 1.287). These assumptions are described, and the basis for them is explained, at SPF 1.288-SPF 1.304.

Directors who approved the license, testified that "it was made very clear to the Directors that we were looking at this license agreement, which had to stand on the merits of the license agreement." (SPX 1225 at 30)(SPF 1.37, 1.49). He said that the Board was assessing the proposal as if there were no settlement. (SPF 1.49). Patricia Russo, another member of Schering's Board, confirmed that the agreement would have "to make sense in and of itself independent of anything else." (CX 1526 at 25)(SPF 1.37, 1.49)(IDF 163).

b. Dr. Levy's Challenge to Mr. Audibert's Review

Dr. Levy testified that, in his opinion, the price of $60 million was grossly excessive and that Mr. Audibert should have done more due diligence before reaching the conclusions he did. From that Dr. Levy extrapolated that, in his opinion, Schering could not really have been paying for Niacor, and must have been paying for something else. This opinion was not supported by the evidence.

(1) Dr. Levy's Lack of Relevant Experience

First, Dr. Levy's expertise to address many of the issues underlying his opinion is questionable at best. He is not an expert in cholesterol-reducing drugs. (SPF 1.254). He is not a cardiologist. (*Id.*). He has not prescribed a cholesterol-lowering drug in twenty years. (*Id*.). And he did not even know what the NIH-sponsored National Cholesterol Education Program ("NCEP") was. (SPF 1.256)(IDF 308).

Dr. Levy had only worked in a pharmaceutical company for a little over four years, and three of those years were the early 1980s. (SPF 1.251). He had no sales responsibility outside of North America in either of his two positions at pharmaceutical companies. (SPF 1.257) And he had never personally converted a New Drug Application filed in the United States into an application for European regulatory approval. (*Id.*).

Moreover, although Complaint Counsel called Dr. Levy to give expert testimony on "the state of knowledge in the pharmaceutical industry concerning sustained-release niacin drugs" in

1997,[8] Dr. Levy confessed on cross-examination that he was *not* an expert on the state of knowledge on that subject. (35 Tr. 8305-06)(SPF 1.255). He claimed only that, through his recent reading of scientific literature, he was an expert on what real experts on that subject were saying at the time. (*Id.*)(SPF 1.255). But he then conceded that that really didn't make him an expert at all: "one doesn't have to be an expert to be able to read the literature." (*Id.* at 8411)(SPF 1.255). And to make matters worse, he proceeded to display a lack of familiarity even with the published literature on sustained-release niacins in 1997 that he claimed to have boned up on. (SPF 1.255–1.256).

(2) Dr. Levy's Testimony that the Payment Was "Grossly Excessive"

Dr. Levy's opinion that the payment for Niacor-SR was "grossly excessive" rested principally on his assertion that Niacor-SR was toxic to the liver. (7 Tr. 1307, 1317)(SPF 1.266). In his expert report, he had written that "[t]he drug showed clear evidence of hepatotoxicity that, unless mitigated, would be unacceptable." (9 Tr. 1774).

But Dr. Levy had mistakenly focused on data showing the liver enzyme elevations of patients at the level of 1.5 times the upper limit of normal. (SPF 1.267). The FDA considers liver enzyme elevations at less than *three times* the upper limit of normal as clinically insignificant. (SPX 267)(SPF 1.267). So Dr. Levy was using the wrong standard in evaluating liver toxicity. And when the correct standard is used, Dr. Levy's principal attack on Niacor-SR falls apart. Indeed, some market leading statins have liver enzyme elevation levels higher than Niacor-SR. *Supra* at 22.

Dr. Levy testified that he thought the FDA standard might be different, however, for classes of cholesterol-lowering drugs other than statins – drugs like niacins or fibrates. (SPF 1.248). But that turned out to be wrong, too. Tricor, a very successful fibrate marketed by Dr. Levy's former employer Abbott Laboratories, is associated with elevations of three times the

---

8 Complaint Counsel's Opposition to Upsher-Smith's Motion to Exclude Rebuttal Witnesses at 8.

upper limit of normal in as many as 13% of patients and with successive elevations at that level in more than 5% of patients. (SPX 1208)(SPF 1.249, 1.270). Tricor is an approved drug, annual sales of which exceeded $271 million in the United States for the first eleven months of 2001. (SPF 1.249, 1.270). After being confronted with his errors, Dr. Levy admitted that “I don’t think anyone can say that an elevation of a couple of enzymes is evidence of liver toxicity.” (9 Tr. 1773)(SPF 1.266).

(3) The Size of Schering’s Upfront Payment

Dr. Levy also claimed that the size of Schering’s upfront payment was suspect. Dr. Levy contended (a) that “[t]he only time when license fees rise above a fairly—a very low level is when there is considerable competitive activity for this—for this product and when the product has enormous upside potential.” (7 Tr. 1326)(SPF 1.356). And Dr. Levy contended (b) that the Niacor-SR upfront payments were out of line with other Schering license deals that he had studied. (SPF 1.338). Both points were wrong.

(a) The evidence showed several other Schering deals involving sizable upfront payments where there was no competitive bidding. For example, Schering signed licenses [X**XX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX].** And in both cases, there were no other bidders. (19 Tr. 4374)(SPF 1.356). Schering made large upfront payments in those cases because “that’s what it took to get the deal done.” (*Id.*).

(b) The evidence showed that, in evaluating a potential licensing deal, Schering focuses not just on the upfront fee, but on the *total investment* that will be required before the product receives regulatory approval. (SPF 1.344)(IDF 299-300). This total investment will usually consist of upfront fees, later milestone fees that must be paid *prior to* regulatory approvals,[9] and

[9] An example would be milestone fees payable upon completion of certain early clinical trials by the licensor. **[(19 Tr. 4454, 4529-30)]**.

research and development costs which will be incurred prior to regulatory approvals (19 Tr. 4365-67)(SPF 1.344, 1.346)(IDF 299-300). Thus, when a proposed licensing transaction is brought before the Schering Board of Directors or Schering-Plough Operating Committee ("SPOC"), the Board or SPOC is always informed, *in writing*, of the anticipated research and development expenditures that will be required before the drug is brought to market. (19 Tr. 4365-67)(SPF 1.346-1.348). Even Dr. Levy had to admit that when making the determination to enter into a license, people look at total investment and not just at the upfront fee. (35 Tr. 8335)(SPF 1.345).

[XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

XXXXXXXX	XXXXXXXXXX	XXXXXXXXXXXXXXXXX
XXXXXXX	XXXXXXXXX	XXXXXXXXX
XXXXXXX	XXXXXXXXXX	XXXXXXXXX
XXXXXXXXX	XXXXXXXX	XXXXXXXX
XXXXX	XXXXXXXXXXX	XXXXXXX
XXX	XXXXXXXXXXX	XXXXXXXXX
XXXXXXXXXX	XXXXXXXXXX	XXXXXXXX
XXXXXXXXXX	XXXXXXXXXXX	XXXXXXXX
XXXXXXXXXX	XXXXXXXXXXX	XXXXXXXXX

XXXXXXXXXXXXXXXXXXXXXX][10]

Under the agreement with Upsher, Schering was not responsible for conducting any clinical trials or other research and development costs necessary to obtain United States approval. Thus, in contrast to the other deals Dr. Levy examined, there were no anticipated research and development costs to be paid by Schering.

10 The figures in this chart are taken from *contemporaneous documents* presented to Schering's Board of Directors or its Operating Committee in connection with their approval of the deals. **[CX 1310; CX 1348; CX 1397; SPX 1269; CX 1651; CX 1412; CX 1467]**.

Moreover, as Complaint Counsel's rebuttal witness, Mr. Egan, explained:

> [T]he up-fronts are really window dressings on one of these deals. Typically a big pharma player will use up-fronts to buy down the upside. … [T]ypically, if you're in a negotiation with a biotech, you put in big up-front payments if you have a very favorable split of the revenues going forward.

(33 Tr. 7983)(SPF 1.340).

Differences among the products, markets, and the needs of the licensors make comparisons of licensing deals difficult. (SPF 1.349). [**XXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX]**

A table comparing the relevant provisions of the Niacor-SR and Remicade licenses is set forth below:

	Niacor-SR (6/97)	**XXXXXXXXX**
Territory	Ex-U.S., Canada & Mexico	**XXXXXXXXXX**
Development Phase	Phase III	**XXXXXX**
Risk	Slight	**XXXXXXXX**
Strategic Fit	Yes	**XXX**
Royalty Paid to Licensor	10%-15%	**XXXXXXX**
Non-Contingent License Fee	$60M	**XXXX**
Milestones Tied to EU Approval	$10M	**XXXX**
Total License Fees / Milestones	$70M	**XXXX**
Peak Year Sales Projections	$140M	**XXXX**
Economic Value @ 13%	$225M-$265M	**XXXXXXXXX**

(SPX 26, at SP 12 00268, 270-271, 273, 275 (Niacor-SR)**; [XXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX]**(SPF 1.354).

Schering valued the Centocor deal in *contemporaneous documents* shown to the Board of Directors at [XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX **XXXXXXXXXXXXXXXXXXX]**(SPF 1.351-1.353).[11] And the amount of money Schering paid Centocor upfront was [X**XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXX**](SPF 1.351). This was partly due to the fact that Schering pays [**XXXXXXXXXXXX**] to Centocor on Remicade sales **[XXXXXXXXXXXX]**, as compared with the 10-15% it would have owed Upsher on sales of Niacor-SR. (7 Tr. 1329; SPX 92, at SP 00195)(SPF 1.352).

(4) The Parties' Post-Deal Conduct

Another purported basis for Dr. Levy's opinion that the Niacor-SR license was a sham was his view that after the agreement was signed, Schering "showed no serious interest in developing and marketing the drug." (7 Tr. 1379)(SPF 1.405). The record proves otherwise. (IDF 316-318). Schering was doing everything one would expect given the terms of its arrangement with Upsher-Smith.

Upsher, not Schering, was to complete the write-ups of the clinical trials, and perform any other clinical work needed to prepare its NDA. (SPF 1.406)(*See* IDF 281-82). Mr. Audibert knew that the two critical pieces of the NDA that would form the basis of Schering's overseas filing, the Integrated Summary of Efficacy ("ISE") and Integrated Summary of Safety ("ISS"), were to be available to Schering in October 1997, permitting Schering to convert those materials into its overseas dossier for filing at the end of that year. (CX 1042 at SP 16 00079)(SPF 1.406). As Mr. Lauda explained, the "plan of action was to let Upsher finish its clinical work, finish its dossier, provide us with the dossier." (19 Tr. 4350)(SPF 1.407-SPF 1.412). Schering would then "convert the NDA or the filing that Upsher was to make in the U.S. into a European format." (*Id.*).

---

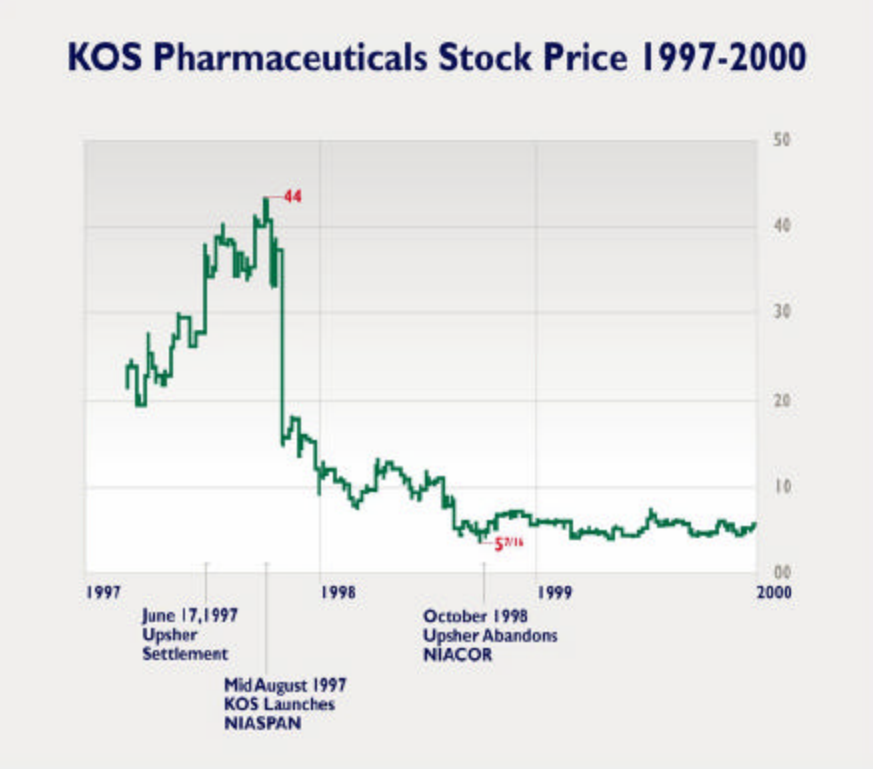
[11] Dr. Levy characterized Remicade as a "billion dollar drug." [**7 Tr. 1468-69**] (SPF 1.353). It certainly is not, at least not yet. **[XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX]**(SPF 1.353). But at the time Schering entered into the license with Centocor, as contemporaneous documents show, its expectations were lower.

Consistent with this plan of action, Mr. Audibert wrote Mr. Halvorsen of Upsher-Smith in August 1997 to arrange a "meeting at Upsher-Smith for the week of September 15th so that our regulatory and clinical people can meet with you to review the Niacor-SR dossier and discuss filing strategies." (SPF 1.410)(IDF 265). Upsher-Smith's dossier was not ready to be reviewed by then, and Schering was assiduous in its follow-up efforts. (*See, e.g.*, SPX 12)(SPF 1.411)(IDF 264-65). Contrary to Dr. Levy's claim that there was "almost no communication regarding Niacor-SR between Schering and Upsher-Smith after the execution of the agreement," (9 Tr. 1823), numerous contemporaneous documents reflect otherwise. (SPF 1.403-SPF 1.412)(IDF 316-318).

Dr. Levy also claims one would have expected to see a "project team" created at Schering consisting of members from Schering's research, regulatory affairs, and marketing departments, and that he was "not sure they had a project team." (7 Tr. 1382; 9 Tr. 1838)(SPF 1.405). But the written record reflects that Mr. Audibert, from Schering's Global *Marketing* department, was conferring with Schering's *research and development*, *regulatory affairs* and *manufacturing* departments, so that a team would be in place when the ISS and ISE were ready. (SPX 243-244)(SPF 1.1.403-1.412).

In November 1997, both Upsher's and Schering's interest in Niacor-SR diminished because they learned that Niaspan was doing very poorly in the marketplace. Kos' product was launched in mid-August 1997, but its first quarter sales results were not announced until November 12, 1997. (SPF 1.419-1.420)(IDF 275). The results were a major disappointment. (23 Tr. 5480)(SPF 1.420)(IDF 275). The day they were announced, Kos' stock price dropped sharply, from a price of $30.94 to $16.56, and the Kos stock price soon reached a level of about $5.00. (USX 1027; 27 Tr. 6867; 10 Tr. 2075-58)(SPF 1.420).

The decline in Kos' stock price, which continued through 1998 and 1999, is dramatically depicted on SPX 2062, which is reprinted here below:



Sales of Niaspan for 1997, 1998, and 1999 were very disappointing. They were significantly below Mr. Russo's projections:

Sales ($) (millions)	1997	1998	1999
Russo	7	48	101
Actual	1.8	16.3	37.9

(CX 550 at SP 002743; SPX 1205)(SPF 1.419). And Mr. Russo's projections were themselves below the market analysts.

Niaspan's poor performance in the marketplace eventually led Upsher to conclude that further investment in Niacor-SR was unwise. (SPF 1.421)(IDF 279-80). Schering drew the same conclusion. (SPX 15; 19 Tr. 4358-60)(SPF 1.424-1.428)(IDF 278,281).

(5) Schering Did the Due Diligence That Was Appropriate

Dr. Levy was also critical about the "due diligence" that was performed on Niacor-SR. Schering, however, did all the due diligence that was appropriate under the circumstances.

The amount of "due diligence" performed before entering into a license agreement is dependent on many factors. (IDF 304). As Mr. Russo explained, "it depends on the nature of the opportunity. If it's an early stage product which is early in development and it's a new and novel compound, we will do a lot. If it's a late stage compound that has, you know, a characterized profile, it has phase III data, clinical data available, and it has a filed NDA, for example, we'll do much less." (15 Tr. 3432)(SPF 1.359-1.363).

Unlike any of the products involved in the other Schering deals Dr. Levy examined, Niacor-SR was a very well known compound whose efficacy had already been established. (19 Tr. 4347; SPF 1.364-1.366, 1.369)(IDF 305). Mr. Lauda testified that it was the most straightforward deal he had ever been involved with at Schering. **[(19 Tr. 4600)]**(SPF 1.364). Mr. Audibert was uniquely and fully qualified to analyze this product (SPF 1.374)(IDF 306), and Complaint Counsel have never seriously contended otherwise.

Perhaps more to the point, Dr. Levy was unable to identify *anything* Schering would have learned about Niacor-SR through exercise of further diligence that would have affected Schering's evaluation. His efforts to come up with something only made him look ridiculous. He stated in his expert report that the liver function data "would have mandated a detailed examination of the effects of Niacor-SR on the liver prior to any consideration of in-licensing the drug. Such detailed examination, in my opinion, would have included, at the least . . . Examination of *liver biopsies in patients treated with Niacor-SR*." (9 Tr. 1785-86)(SPF 1.272)(IDF 313)(emphasis added). To perform such liver biopsies, Upsher would have been required to track down the patients from the long-completed clinical trials; redose them with Niacor-SR; and then obtain their consent to perform a biopsy. (SPF 1.273)(IDF 314). A biopsy entails the use of an enormous needle that goes through the skin and tissue and pulls out a plug

of the patient's liver. (9 Tr. 1796)(SPF 1.273). When this was brought to his attention during cross-examination, Dr. Levy admitted that he had "probably overstated" the opinion expressed in his report and that it is doubtful that the patients from Upsher's clinical trials would agree to liver biopsies. (SPF 1.273)(IDF 314). And, in any event, the liver enzyme elevations for Niacor-SR were unremarkable. *Supra* at 22.

Dr. Levy also asserted that Schering should have conducted a detailed examination of the results of animal studies, which he assumed must have been required by the FDA. In fact, however, animal studies had not been required, and there was therefore no animal data to examine. (CX 907)(SPF 1.274).

Finally, Dr. Levy and Complaint Counsel suggest that Schering, had it done more "due diligence," would have discovered Upsher-Smith's communications with the FDA about the need for a specific type of pharmacokinetic study. (7 Tr. 1388-89)(SPF 1.385). But the fact that a pharmacokinetic study remained to be done would have had no impact on Schering's evaluation of Niacor. (19 Tr. 4516-17, 21)(SPF 1.385). Dr. Levy admitted that, for Schering, doing a pharmacokinetic study is "like falling off a log." (7 Tr. 1388)(SPF 1.385)(IDF 303). Upsher's pharmacokinetic study was scheduled to take 17 days to complete. (IDF 303). Knowing that it remained to be done before approval would have been unimportant to Schering. (SPF 1.385)(IDF 303).

In short, Dr. Levy was unable to make the case that Schering, had it done something more in the way of due diligence, would have identified *any* problem with Niacor-SR that would have affected its evaluation. No amount of due diligence would have predicted the market's extremely poor reaction to Niaspan, which was what caused Upsher-Smith and Schering to abandon their investments in the product. (*Supra* at 32).

Judge Chappell concluded that Dr. Levy's testimony was "contradicted by the greater weight of the evidence." (ID 109). He also rejected his testimony because "he lacked expertise in the area of cholesterol-lowering drugs and niacin." *Id.*

ARGUMENT

Complaint Counsel Failed to Prove Any Net Payment From Schering To Upsher: The Niacor-SR License Was A Fair Value Transaction

Complaint Counsel referred to the fair value issue as the "pivotal issue" in the case. (*Supra* 2 n.1). They conceded that if the $60 million was a *bona fide* fair value license for Niacor-SR, the Upsher settlement was lawful. That issue consumed most of the trial. The Administrative Law Judge considered the evidence offered by both sides, made forty pages of detailed findings, and concluded that "[a]bundant evidence at trial established that the $60 million paid by Schering was fair value for Niacor-SR and the other licensed products." (ID 108). Judge Chappell found that the fact testimony showed that the license was "a *bona fide* arms length transaction." (ID 107). He specifically found that this fact testimony, consisting mainly of the Schering witnesses who negotiated, evaluated and approved the Niacor-SR license and who testified and were cross-examined live before him, was "unrebutted and *credible*." (ID 107)(emphasis added).[12]

On appeal, Complaint Counsel scarcely mention either the evidence introduced on the fair value issue or the Judge Chappell's extensive findings. They take no issue with the fact that Schering had a demonstrated and *documented* interest in a sustained-release niacin product *prior to* the time it negotiated the Niacor license with Upsher. They take no issue with Mr. Audibert's sales projections for Niacor-SR, nor do they dispute that these projections represented his best business judgment at the time. They take no issue with Schering's documented conclusion that those projections gave the rights to Niacor-SR a net present economic value of $225-265 million.

---

[12] Because the fact that the $60 million was payment for Niacor-SR was so clearly documented at the time of the transaction, Complaint Counsel were forced to claim repeatedly that the transaction was a "veil" or a "disguise" devised at the time of the transaction to conceal a payment made for some other purpose. *See* Complaint Counsel's Statement of the Case at 5 ("disguise"); Complaint Counsel's Trial Brief at 6 ("disguise") and 26 ("veil"); Complaint Counsel's Opening Statement, 1/23/02 Tr. 23, 24 ("disguise"). This claim would have placed on Complaint Counsel a higher burden applicable to parties who allege fraud. *E.g., White v. National Steel Corp.*, 938 F.2d 474, 490 (4th Cir. 1990). Complaint Counsel proved no such fraud or bad faith on Schering's part, and have now largely abandoned their claim that the Niacor-SR license was a "veil" or a "disguise." *See* CAB at 24.

They scarcely mention their licensing expert, Dr. Levy. And they do not dispute that Schering made a nearly contemporaneous payment of [**XXXXXXX]** to a company called Centocor for the rights to a product Schering valued at about half of Niacor-SR.

They renew only a few of the factual arguments they made unsuccessfully below, and devote the remainder of their brief to a technical reading of the contract. None of these arguments support a decision to overturn Judge Chappell's factual determinations.

A. Burden of Proof and Standard of Review

"Counsel representing the Commission . . . shall be required to sustain the burden of proof." Commission Rule 3.43(a), 16 C.F.R. § 3.43(a). At trial, Complaint Counsel had the burden of proving that the $60 million was not a *bona fide* fair value payment for the rights to Niacor-SR.

On appeal, Complaint Counsel face an additional hurdle. The question whether the $60 million was a *bona fide* fair value payment depended, in part, on the credibility of the witnesses who appeared before Judge Chappell. An Administrative Law Judge's findings on issues turning on the credibility of witnesses appearing before him are ones to which the Commission has traditionally accorded great deference. "[I]t is the ALJ, as trier of the facts, who has lived with the case, and who has had the opportunity to closely scrutinize witnesses' overall demeanor and to judge their credibility." *In re Horizon Corp.*, 97 F.T.C. 464, 857 n.77 (1981). *See also In re Diener's Inc.*, 81 F.T.C. 945, 978-79 (1972) ("The credibility of witnesses must be left in large part to the hearer of the testimony, a proposition too elementary to require citation of authority") (quotations omitted); *In re Certified Bldg. Prods., Inc.*, 83 F.T.C. 1004, 1028 (1973) ("Ordinarily, we leave undisturbed those findings of an ALJ derived from his observations of the demeanor of witnesses"); *In re Southern States Distrib. Co.*, 83 F.T.C. 1126, 1172 (1973) ("Evaluation of witness credibility, however, is a matter for which the administrative law judge is best situated, and absent good cause to challenge that evaluation, we will not disturb it").

Courts of appeals reviewing the Commission's decisions take a similar view. *See Cinderella Career & Finishing Schools, Inc., v. FTC*, 425 F.2d 583 (D.C. Cir. 1970). In *Cinderella,* the court referred to live testimony before an ALJ, and said that it is as unreasonable for "the Commission to claim a right to ignore that evidence and . . . to decide a case de novo as it would be for this court to claim a right to ignore the findings of fact and conclusions of law of a district court in a proceeding here, substituting the judgment of this court on a cold record for that of the finder of the fact below." *Id*. at 587-88.

In an effort to get around this problem, Complaint Counsel contend that Judge Chappell's findings on the fair value issue are based on self-serving testimony unsupported by contemporaneous documents. CAB at 23-24. This contention is not true. All of the major findings in the Initial Decision are strongly supported by contemporaneous documents. Schering's pre-existing interest in sustained release niacin; Schering's sales projections for Niaspan; Schering's sales projections for Niacor-SR; and the Board of Director's approval of the $60 million Niacor-SR license as a transaction which stood "on its own merit independent of the settlement," are all examples of major facts recorded in contemporaneous documents.

There is no basis upon which to set aside Judge Chappell's credibility findings, or indeed any of his findings, on the fair value issue.

B. Complaint Counsel Try to Circumvent the Fair Value Findings

Complaint Counsel's first argument in their Appeal Brief amounts to an effort to side step the fair value issue. They argue that since the Niacor-SR license was partly designed to fill Upsher's need for cash during the period between the settlement and the September 1, 2001 entry date, the $60 million payment must have been a payment "for delay." (CAB 25-27). But this is wrong, as their own expert conceded.

The relevant facts are undisputed. Early in the negotiations, Schering understood Upsher to be asking for a payment for delay. (*Supra* at 9-10). Schering refused to make or discuss such a payment. (*Id.*). The parties then decided to try to settle by compromising the entry date. Their

discussions centered on an entry date of September 2001 as a fair compromise. (*Supra* at 10). Mr. Troup, Upsher's CEO, expressed a strong desire for cash flow to replace the cash flow he had hoped to receive from sales of generic K-Dur 20 had Upsher won the patent case. (*Id.*). Schering told Mr. Troup it would discuss other business deals with Upsher, so long as they "stood on their own two feet." The parties then started exploring the Niacor-SR license. See *supra* at 10-11.

The Niacor license was presented to the Board of Directors. The Board was told that the Niacor license opportunity had come up during settlement discussions partly because of Upsher's expressed need for cash flow in the near term. The Board was also told that the Niacor-SR license should be approved only if it "stood on its own merit independent of the settlement." (CX 338). The Board reviewed the contemporaneous written evaluation and approved the license on that basis. (*Supra* at 24-25).

This was entirely appropriate, as Complaint Counsel's expert conceded. Complaint Counsel's expert was asked on cross-examination what was wrong with a side transaction designed to meet Upsher's desire for cash "*now*," – a desire resulting in part from the fact that it was giving up, under settlement, the *possibility* of cash flow in the near term from its generic version of K-Dur. Professor Bresnahan replied that "if they stop at a fair market value transaction, generally I don't think there's a problem." (6 Tr. 1220).

So Complaint Counsel's latest argument, based on Upsher's cash needs, simply brings us back again to the "pivotal issue" of fair value. If the license was for fair value, that is the end of the matter.

C. Complaint Counsel's Limited Challenge on Fair Value

On appeal, Complaint Counsel make only a few cursory challenges to Judge Chappell's findings on the fair value issue. We respond to each such challenge below.

1. Size of the Upfront Payment

Complaint Counsel argues once again that the $60 million was too much to pay for Niacor-SR, even given its estimated net present value of from $225-$265 million. They urge that the upfront payment of the $60 million was out of line with other upfront payments Schering had made in other deals. CAB at 32. This is refuted by undisputed evidence. In the case of Remicade, for example, [**XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX**]. (SPF 1.351). In the case of Niacor-SR, Schering paid $60 million for the rights to a product it valued at $225-265 million. There is nothing out of line about that. Schering's licensing expert testified that a major pharmaceutical company would pay up to $100 million for a product with Niacor-SR's estimated net present value of $225-265 million. (SPF 1.328)(IDF 260).

Moreover, the evidence shows that, when the total investment (upfront fees, milestone fees, and R&D) Schering would have to make prior to regulatory approvals is considered, the Niacor-SR license is average. *See* chart at p. 28, *supra*.

2. The Non-Contingent Nature of the Upfront Payment

Complaint Counsel argue that the non-contingent nature of the $60 million upfront payment is suspicious. CAB at 33. This argument is utterly without substance. All upfront payments are non-contingent. This was true of all the other deals analyzed by Dr. Levy, including the Remicade deal discussed above.

3. Due Diligence

Complaint Counsel also assert that Schering, had it been seriously interested in Niacor-SR, would have done more in the way of due diligence. (CAB at 33). But the amount of due diligence performed before entering into a licensing agreement depends on the particular license under consideration. (SPF 1.359-1.360). Here, niacin was a well-known drug, with well-known cholesterol-reducing properties, and was recommended for treatment of hypercholesterolemia by the NIH sponsored NCEP. (*Supra* at 19-20). Schering had already studied the cholesterol drug

market extensively both here and abroad in connection with its blockbuster pipeline drug, ezetemibe. (*Supra* at 18-19). Schering had already done a significant amount of diligence concerning *sustained-release* niacin in connection with its evaluation of Niaspan. (*Id.*). And, as to Niacor-SR, Upsher had given Schering detailed data from the Niacor-SR clinical trials showing that it was safe and effective. (SPF 1.232, 1.237-1.242, 1.245-1.247). Finally, Complaint Counsel failed to come up with anything which further diligence would have uncovered about Niacor-SR that would have affected Schering's decision. (*Supra* at 33-34).

4. The Kos Negotiations

Finally, Complaint Counsel argue that the breakdown in Schering's negotiations with Kos somehow shows that Schering's interest in Niacor-SR was not genuine. (CAB at 33-35). But the Kos negotiations show precisely the opposite: that Schering, before engaging in any discussions with Upsher and for reasons concededly unconnected to any patent litigation, was seriously and genuinely interested in a sustained-release niacin product. Schering's sales projections for Kos' Niaspan, which have never been challenged by Complaint Counsel, are consistent with those that were generated by Mr. Audibert for Niacor-SR. (*Supra* at 23). And Schering made a significant offer to Kos under which Schering committed to spend *$30 million* to promote Niaspan in the first year alone. (SPF 1.144). The Kos negotiations demonstrate the genuineness of Schering's interest in sustained-release niacin, not the opposite.

The Kos transaction was less appealing than the Niacor-SR transaction for several reasons. First, it was a co-promotion arrangement rather than a license. Schering was to receive *at most* 50 percent of the profits from Niaspan sales, making the Kos co-promotion deal worth less than half as much as the Niacor-SR license deal. (SPF 1.390). Second, Schering had to share control of the marketing strategy with Kos. (SPF 1.392). And third, Kos was proving very difficult to work with. (*Supra* at 15). All that can be gleaned from the Kos negotiations is that the Upsher license was a more attractive deal for Schering.

D. Complaint Counsel's Other Arguments

1. The Executive Summary

Complaint Counsel cite to an "executive summary" document which considers various "options" to settlement with Upsher. Complaint Counsel call it the "blueprint" for the settlement. (CAB at 28-29).

Complaint Counsel fail to mention the two critical facts about this document. First, the document states on its face that any settlement with Upsher must pass "all legal and regulatory constraints (e.g., F.T.C.)." Second, the option which Schering chose – a patent-shortening settlement with a *fair value* side transaction[13] – is one which Complaint Counsel conceded at the trial *does* pass regulatory constraints.

Once again, Complaint Counsel's argument just brings us back to the fair value issue.

2. Paragraph 11 of the Agreement

Complaint Counsel rely on Paragraph 11 of the Agreement. (CAB 29-30). Paragraph 11 sets forth the amounts Schering agreed to pay Upsher, and describes them as "consideration" for "the licenses, rights and obligations described in paragraphs 1 through 10 above." Paragraphs 1 through 10 cover all of the material terms of the agreement including the split of the patent life and the rights to Niacor-SR. Complaint Counsel argue that Paragraph 11 shows that the $60 million was not a *bona fide* payment for Niacor-SR and that some portion of it must have been for delay. Paragraph 11 shows no such thing.

The Niacor-SR license was an integral part of a single agreement that settled the patent lawsuit. In that sense, it may be said to be "consideration" for the entire agreement. "[T]he word 'consideration' is often used in different senses . . . ." 3 Samuel Williston, *A Treatise on*

---

13 *See* Option IV:

> IV. Review UPS portfolio and purchase pipeline products or in-line portfolio for SGP to promote.
>
> *Estimated value—depends on products purchased*

(CX 283)(emphasis added).

the Law of Contracts § 7:2, at 11 (4th ed. 1992). But it would be completely unreasonable to interpret the agreement to mean that the parties viewed the $60 million to be something other than a fair value payment for the license rights to Niacor-SR. To the contrary, the $60 million payment is referred to in Paragraph 11 as a "royalty." Royalty payments, as Complaint Counsel's licensing expert himself explained, denote payments for "a pharmaceutical *license*." *See also Sierra Club, Inc. v. Commissioner*, 86 F.3d 1526, 1531 (9th Cir. 1996) (the term "'royalty' commonly refers to a payment made *to the owner of property* for permitting another to use the property"). In this case, the *property* consisted of the rights to Niacor-SR, and the *owner* was Upsher. If the language of the agreement says anything about the fair value issue, it is that the $60 million was a *royalty* in payment to Upsher for the license rights to Niacor.

Moreover, the agreement did not become a contract until it was ratified by Schering's Board of Directors. As set forth more fully *supra* at 24-25, the Board approved the payments only on the understanding that the payments were fair value payments for the Niacor-SR license.

Finally, the negotiation history makes clear that Schering was insistent that it would pay money to Upsher-Smith only for licensing deals that "stand on their own two feet." (15 Tr. 3544). John Hoffman, the Schering in-house lawyer who negotiated the settlement, testified unequivocally that interpreting paragraph 11 to mean that the money was other than fair value for the Niacor-SR license would be "contrary to every discussion" the parties had. (*Id.* at 3565)(SPF 1.40). Under New Jersey law, which governs the interpretation of the agreement, CX 348 at USL 03184, all contracts are to be interpreted in a manner that is consistent with their intended meaning—even when the contract on its face is free from ambiguity:

> Evidence of the circumstances is always admissible in aid of the interpretation of an integrated agreement. This is so even when the contract on its face is free from ambiguity. The polestar of construction is the intention of the parties to the contract as revealed by the language used, taken as an entirety; and, in the quest for the intention, the situation of the parties, the attendant circumstances, and the objects they were thereby striving to attain are necessarily to be regarded.

Halper v. Halper, 164 F.3d 830, 840-41 (3d Cir. 1999)(applying New Jersey law); *accord Onderdonk v. Presbyterian Homes*, 425 A.2d 1057, 1063-64 (N.J. 1981).

As Judge Chappell found, no fact witness testified that the payments were not for the licensing rights. (IDF 162). The agreement may not be interpreted in the manner Complaint Counsel suggest in light of the evidence surrounding the negotiations.

3. Paragraphs 3 and 12 and Force Majeure

Complaint Counsel make a complex argument based on Paragraphs 3 and 12 of the agreement, which lead them to assert that the $60 million royalty payment was linked to Upsher's agreement to stay off the market until September 2001, rather than being linked to the rights to Niacor. CAB at 31. This claim is directly refuted by the very provisions on which Complaint Counsel rely.

Paragraph 12 provides that Schering does not have to make the up front payments *if the license rights "granted to SP licensee"* are declared invalid. The license rights granted to SP Licensee refer to the rights to Niacor. Paragraph 12 thus links the payments directly to *Niacor*. Paragraph 3, which deals with Upsher's rights to market its generic version of K-Dur 20, makes no reference to the payments. So it provides no link between the payments and Upsher's agreement to stay off the market.

The force majeure clause, which is contained in Paragraph 20 and provides that failure to perform obligations under the agreement, *other than payment obligations*, shall not constitute a default if the failure is due to an act of God, is a standard contract clause that appears *verbatim* in other Schering agreements. [**XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXX]**(SR-CPF 180).

4. The Settlement's Effects on Third Parties

The Complaint alleges that the settlement had the effect of blocking other would-be generic manufacturers until March 2002, because of the 180-day "first filer" exclusivity provisions of the Hatch-Waxman Act. Several points should be made.

(1) At the time of the Upsher settlement, the relevant FDA regulation provided that the first filer *lost* its 180-day exclusivity rights by settling. 21 C.F.R. § 314.107(c)(1) (1998)(SPF 1.442-1.444). The regulation was appealed approximately a year later. However, it was unclear at the time of the settlement, and it remains unclear today, whether the settlement blocked third parties. (*See* SPF 1.450-1.456, 1.466-1.472).

(2) There is no evidence in the record that any third parties would have been able to market a generic version of K-Dur 20 prior to March 2002, whether Upsher's first-filer status blocked third parties or not. (SPF 1.499-1.507).

(3) Whatever effect Upsher's first-filer status had on third parties, it is an effect created by law. (SPF 1.490-1.493). And Complaint Counsel have stated here[14] and at trial[15] that if the Upsher settlement agreement is otherwise lawful, "the Complaint does not charge that this additional effect [from the 180-day exclusivity provisions] created an independent violation."

5. The Settlement's Provisions Regarding Other Potassium Chloride Tablets

The Complaint alleges that the settlement agreement prevented Upsher from marketing until September 2001 not only Klor-Con 20 but any other microencapsulated sustained-release potassium chloride tablet. Complaint ¶ 44. The product at issue in the Schering/Upsher patent lawsuit was Klor-Con M20. When the parties settled, they wanted ensure they were not back in court litigating a nearly identical patent case about another Upsher product presenting some of

---

14 CAB at 63-64.

15 *See* Complaint Counsel's Opposition to Upsher-Smith's Motion to Dismiss at 7 n.20.

the same issues. They negotiated a clause in the settlement agreement tailored to address this concern. (*See* SPF 1.33).

Assuming the settlement agreement is otherwise lawful, this provision expanding its coverage to a broader category of products is reasonable. Complaint Counsel's economist expert, Professor Bresnahan, expressly conceded this. (*See* SPF 1.508-1.509). Complaint Counsel below conceded, as had its expert, that this provision of the agreement is not alleged to be "an independent violation." *See* Complaint Counsel's Opposition to Upsher-Smith's Motion to Dismiss at 7 n.20.

Moreover, there is no evidence that Upsher had either the intention or the capability of developing or marketing any other microencapsulated sustained-release potassium chloride supplement. (SPF 1.508; UPF 905-06).

CONCLUSION

Complaint Counsel cannot prevail in the Upsher case unless they can show that the $60 million was something other than a fair value payment for the rights to Niacor-SR and the other licensed products. Judge Chappell has clearly found that the $60 million was a *bona fide* fair value payment for the Niacor-SR license. His finding rests on credibility determinations as well as contemporaneous documents. Complaint Counsel have come up with no basis for setting aside those findings.[16]

II. THE ESI SETTLEMENT

FACTS

At trial, Complaint Counsel introduced very little proof concerning the ESI settlement. No fact witnesses were called live in connection with it. One expert testified about it, but only for about ten minutes. Similarly, in their Appeal Brief, Complaint Counsel devote only a few

---

[16] Complaint Counsel also failed to prove its case against the Upsher settlement for the legal and policy reasons set forth *infra* at 55-74. Schering joins in and adopts the points made in Upsher's Appeal Brief.

pages to the ESI case. (CAB 13-15, 36-37). They do not mention the role in the settlement played by the trial judge and the United States Magistrate Judge. We set forth the facts concerning the ESI settlement in the next eight pages.

A. Court Supervised Mediation

In 1990, Congress passed the Civil Justice Reform Act, 28 U.S.C. § 471 *et seq.* (2000), which encouraged federal courts to use various techniques to alleviate congestion, including conferences between the court and the parties to explore the possibility of settlement in complex cases. In 1998, responding to increased concerns about overwhelmed court dockets, Congress enacted the Alternative Dispute Resolution Act, 28 U.S.C. §§ 651-658 (2000), which requires every federal court to implement an alternative dispute resolution program.

The evidence showed that Schering and AHP submitted to such court supervised mediation. Judge DuBois initiated the mediation in the fall of 1996. (IDF 332)(SPF 2.4, 2.6). Magistrate Judge Rueter served as the mediator. (IDF 332)(SPF 2.7).[17]

There were at least six formal mediation sessions in Judge Rueter's courtroom or chambers over a fifteen-month period. (*See* IDF 332). Each lasted several hours. At the first session, Judge Rueter heard argument lasting an hour or two from both parties on the merits of the case. (SPF 2.13). Thereafter he met with the parties separately in his chambers during each session, passing settlement proposals back and forth, always urging the parties to settle. (SPF 2.13).

One proposal that was frequently mentioned was that Schering should pay ESI a substantial sum, an amount of up to $100 million, to settle the case. (SPF 2.14, 2.17, 2.26, 2.31-2.32, 2.38). Schering repeatedly declined, telling Judge Rueter that Schering believed such payments raised antitrust concerns. (*E.g.*, 11 Tr. 2510-11, 2516, 2520; 11 Tr. 2575-76, 2580-84; 7 Tr. 1429-30; 12 Tr. 2605, 2613; SPX 1260 at 131:13-132:9)(SPF 2.17, 2.26-2.33, 2.39-2.40).

---

[17] The ESI settlement thus may be subject to *Noerr-Pennington* protection. *See A.D. Bedell Wholesale Co. v. Phillip Morris, Inc.*, 263 F.3d 239, 254 (3d Cir. 2001)("Freedom from the threat of antitrust liability should apply to settlement agreements as it does to other more traditional petitioning activities"), *cert. denied*, 122 S. Ct. 813 (2002).

Because of Schering's refusal to consider making any payment to ESI, mediation efforts came to a standstill in the spring of 1997. (SPF 2.21).

Mediation resumed in the summer of 1997 at Judge DuBois' urging. (SPF 2.22). In August, Schering brought Charles F. "Rick" Rule, former Assistant Attorney General in charge of the Antitrust Division, to a mediation session. (SPF 2.23-2.24). Mr. Rule explained why the proposal for Schering to pay ESI to stay off the market raised antitrust concerns. (11 Tr. 2580-84)(SPF 2.26-2.33).

At a mediation session in October 1997, John Hoffman, Staff Vice President and Associate General Counsel, Antitrust, at Schering once again explained that, for antitrust reasons, Schering was unwilling to make a large payment to settle the case. (SPF 2.37-240). Throughout these mediation sessions, Mr. Hoffman and others told Judge Rueter that Schering wished to try the case. (12 Tr. 2612-13)(SPF 2.17, 2.40, 2.74).

Schering also expressed doubts, at the October 1997 mediation session, that ESI actually had a generic version of K-Dur 20 that FDA would approve. (SPF 2.41). In early December 1997, Schering obtained from ESI long-requested information concerning problems ESI had in demonstrating that its generic was "bioequivalent" to K-Dur 20, as FDA law requires. (IDF 349)(SPF 2.47-2.49). The information showed that FDA had twice rejected ESI's bioequivalence studies and that ESI had only begun its most recent effort to establish bioequivalence on December 8, 1997. (IDF 249)(CX 469)(SPF 2.49).[18]

In mid-December 1997, Schering offered to settle the case by dividing the remaining patent life with ESI. (SPF 2.50-2.51). Schering proposed, in a letter dated December 17, 1997, a settlement under which ESI's product could enter the market December 31, 2003, and not before. (IDF 350-51)(CX 470)(SPF 2.50-2.51). Schering had been having discussions for some time

---

[18] Contrary to Complaint Counsel's appeal brief at 14, it is inaccurate to say that "Schering demanded and received *assurances* that AHP's product was approvable" (emphasis added). Schering demanded and received information about AHP's product, which confirmed Schering's suspicions that AHP was having great difficulty in establishing bioequivalency to K-Dur 20, and strengthened Schering's view that AHP would *not* have an approvable product. (SPF 2.41, 2.44-2.45, 2.47-2.49, 2.74, 2.77-2.80; SR-CPF 875)(CX 474).

with ESI about licensing generic drugs that ESI had in development. (*See* IDF 343-344)(SPF 2.35-2.36). In its December 1997 letter, Schering also offered to acquire the rights to generic versions of enalapril and buspirone, two products which ESI had in development, for $5 million. (IDF 352)(CX 470)(SPF 2.53).

ESI responded five days later. (IDF 353)(CX 473)(SPF 2.54). ESI accepted the settlement framework proposed by Schering, and agreed with the December 31, 2003 entry date, with the proviso that it could enter the market sooner if Upsher did. (IDF 353)(SPF 2.54). ESI demanded a cash payment of $55 million for the license rights to Enalapril and Buspirone, a price considerably higher than the value of these products. (CX 473)(SPF 2.56, 2.71).

The final mediation sessions occurred on January 22 and 23, 1998, in conjunction with a *Markman* hearing held on January 21 and 22, 1998. (IDF 357)(11 Tr. 2529)(SPF 2.60). A *Markman* hearing is a hearing at which evidence is taken and argument is heard so that the Court can interpret the claims of the patent at issue in the lawsuit. (IDF 357)(SPF 2.60).

At the beginning of the *Markman* hearing Judge DuBois noted that he had gotten "report after report" from Judge Rueter regarding the parties' settlement negotiations. (SPX 687, at ESI HRG 000164)(SPF 2.61). Judge DuBois expressed "a bit of anger" that the parties had not yet settled the case, after spending a "tremendous amount" of the Court's time and the clients' money. (CX 1482 at 80:5-81:9; SPX 1222 at 81:10-18; SPX 687, at ESI HRG 000164)(SPF 2.61).

The parties had another settlement conference with Judge Rueter scheduled for 2 p.m. on the second day of the Markman hearing. (IDF 358)(SPF 2.62). Judge DuBois encouraged the parties to attend the settlement conference, stating that "I hope it works." (SPX 687, at ESI HRG 000126)(SPF 2.62). Judge Dubois told the parties "to stay as long as you think you have to stay [with Judge Rueter], and I'll remain this evening as long as it takes to finish this matter." (SPX 687, at ESI HRG 000127)(SPF 2.62).

Later that day, the parties returned to appear before Judge DuBois. (SPF 2.63). Judge DuBois mentioned that on the following day, Friday, January 23, 1998, another settlement

conference was scheduled with Judge Rueter at 2:30 p.m. Judge DuBois again urged the parties to settle the case:

> You can repay the Court for its indulgence and patience by focusing hard on compromising and narrowing whatever differences remain between you in getting this case settled.

(SPX 687, at ESI HRG 000138)(SPF 2.64).

Judge DuBois explained that he wanted the parties to settle and that he did not want to have to try the patent case:

> We're talking about the conciliatory services that the Court offers, and that's what I want you to use to resolve the case. I don't want to have to adjudicate either this case or the two-week long or longer trial of this case. I want you to try to do it.

(SPX 687, at ESI HRG 000139)(SPF 2.65).

The final mediation session began late on January 23, in Judge Rueter's chambers and continued well into the evening. (IDF 359)(SPF 2.69). The Schering representatives were outside counsel, Anthony Herman, in-house counsel, John Hoffman and Susan Lee, and business executive, Martin Driscoll. (IDF 360)(SPF 2.70). Mr. Herman and Ms. Lee were present in Judge Rueter's chambers. (SPF 2.70). Mr. Hoffman was at home and participated intermittently by telephone. (IDF 360)(12 Tr. 2618-19)(SPF 2.70). Mr. Driscoll was at a New Jersey Nets game with his sons and participated intermittently by cell phone. (IDF 360)(12 Tr. 2706-07)(SPF 2.70).

Schering had already made clear that it would, under no circumstances, agree to an entry date earlier than January 1, 2004. (CX 1482 at 99:17-100:6; SPX 1222 at 101:9-17; CX 1492 at 136:16-137:4)(SPF 2.57).[19] And ESI had agreed to the entry date of January 1, 2004. (IDF 356, 261)(12 Tr. 2640, 2618-20; 11 Tr. 2532-33)(SPF 2.71). Further, a price of $15 million had been agreed to for the rights to Enalapril and Buspirone. (IDF 361)(SPF 2.71). However, ESI was still demanding money simply to settle the case. (IDF 362)(11 Tr. 2533)(SPF 2.72).

[19] At some point, the December 31, 2003 entry date had been moved one day forward to January 1, 2004. (SPF 2.55, 2.57).

Judge Rueter suggested that Schering pay ESI $5 million, which he characterized as "nothing more than legal fees." (11 Tr. 2533; SPX 1266 at 125:15-126:7)(SPF 2.72). When Mr. Herman rejected that idea, stating that he wanted to try the case, Judge Rueter asked permission to call Mr. Driscoll and Mr. Hoffman. (*See* IDF 362)(11 Tr. 2533)(SPF 2.72).

Judge Rueter called Mr. Driscoll during the second quarter of the basketball game. (SPF.2.73). The judge told him that there had been a hearing that day, and that Schering had "a good day," but that he had been instructed by the judge to get a settlement that night. (12 Tr. 2707; SPX 1231 at 105:10-16; SPX 1239 at 112:20-113:3)(SPF 2.73).

Mr. Driscoll told Judge Rueter that he did not want to settle, and that he did not want to be on the phone talking about settlement. (12 Tr. 2708-10)(SPF 2.74). Mr. Driscoll also explained that he did not think ESI had an approvable drug. (SPF 2.74).

Judge Rueter called Mr. Hoffman at home. (12 Tr. 2618-19)(SPF 2.75). Judge Rueter told Mr. Hoffman that Schering could "at least" pay ESI $5 million. (12 Tr. 2620)(SPF 2.75). Judge Rueter characterized the $5 million payment as being in the nature of "legal fees." (12 Tr. 2620, 2643)(SPF 2.75). Mr. Hoffman agreed to a $5 million payment. (IDF 362)(12 Tr. 2620; 11 Tr. 2534)(SPF 2.75).

ESI continued to insist on another $10 million. (IDF 362)(SPF 2.76). Judge Rueter called Mr. Driscoll again. (SPF 2.76). Mr. Driscoll testified that he came up with a concept during his conversation with Judge Rueter under which Schering would pay ESI up to $10 million but only if ESI received FDA approval by a certain date. (IDF 363)(12 Tr. 2712; CX 1494 at 110:9-17; 12 Tr. 2620-21; CX 1492 at 156:14-157:2)(SPF 2.77). When Mr. Driscoll suggested this, he thought ESI would not get its drug approved in time. (*See* IDF 364)(12 Tr. 2713, 2722; CX 1509 at 104:4-21; CX 1482 at 109:20-23)(SPF 2.78).

Judge Rueter then called Mr. Hoffman and discussed this settlement proposal, which has been described as a "bet". (SPF 2.79). Judge Rueter told Mr. Hoffman that Schering should "put [its] money where [its] mouth is." (12 Tr. 2620; SPX 1239 at 114:19-25; 11 Tr. 2535)(SPF

2.80). Judge Rueter stated that if Schering was right about ESI's inability to get FDA approval, "this won't cost you anything." (12 Tr. 2621; 11 Tr. 2535)(SPF 2.80).

Schering eventually agreed to this term. (SPF 2.81). At this point, there was an agreement in principle. (11 Tr. 2537; 12 Tr. 2621)(SPF 2.81). Judge Rueter asked the parties to write up the terms and initial or sign them that night. (IDF 365)(SPF 2.83). Mr. Heller, counsel for ESI, hand wrote the settlement principles with Schering's representatives and Judge Rueter "sort of clustered around him." (*See* IDF 365)(11 Tr. 2537, 2488-89; CX 472)(SPF 2.83).

The two-page handwritten agreement in principle, dated January 23, 1998, was signed by Mr. Heller, outside counsel for ESI, and Susan Lee, director of patent litigation for Schering. (IDF 366)(CX 472)(SPF 2.84). Judge Rueter was present at the preparation and signing, looking over the shoulder of Mr. Heller. (SPF 2.84). Judge Rueter was aware of all the terms in the January 23, 1998 handwritten agreement, including the payments from Schering to ESI. Indeed, he had proposed several of the terms. (11 Tr. 2489)(SPF 2.88).

In a letter dated January 26, 1998, Judge DuBois congratulated counsel on settling the case. (CX 491)(SPF 2.90). Judge DuBois wrote:

> Congratulations on getting this case settled. As you know, the settlement resulted in a resolution of the dispute that accommodated the interests of the parties, but which could not have been awarded by the Court at trial. It represents a job well done.

(CX 491)(SPF 2.90).

B. No Proof of Anticompetitive Effects

In light of these facts, which were undisputed, proof of harm to competition is required before condemning this settlement under the antitrust laws. (ID 101-02). As Professor Hovenkamp has explained:

> [T]he general policy of the law is to encourage settlements rather than litigation …. As a result, some agreements that would be unlawful if undertaken in the absence of a reasonable dispute may be lawful when used to settle a bona

> fide dispute. In this category are agreements whose outcomes are no more anticompetitive than a likely outcome of intellectual property litigation permitted to run its course.

12 Herbert Hovenkamp, *Antitrust Law* ¶ 2046, at 265-66 (1999).

At a minimum, Complaint Counsel had to prove, as they promised Judge Chappell they would, *see infra* at 60-61, either that the settlement delivered less competition than some available alternative settlement without a payment, or that the settlement delivered less competition than continued litigation. (ID 103). They introduced *no* evidence on either point. (*See* ID 103).

In *its* case, Schering came forward with proof that it would have won the patent case; and therefore that the judicially supervised settlement agreement provided *more* competition than would litigation. Schering introduced testimony by Charles Miller, an experienced patent litigator, who had reviewed the record in the patent case, including the positions of the parties and the evidence the parties were prepared to offer at the trial. Mr. Miller testified that Schering's case against ESI's generic version of K-Dur was very strong. (15 Tr. 3323, 3351). And he testified that, in his opinion, the January 1, 2004 entry date in the settlement agreement fairly reflected the strength of Schering's case. (15 Tr. 3369). A more detailed description of Mr. Miller's opinion and its support is contained in Findings 3.511-3.515 through 3.563-3.566.

Mr. Miller's opinion stands unrefuted. Complaint Counsel retained its own expert patent litigator, Martin Adelman, to review the record in the patent case and testify in rebuttal to Mr. Miller. (32 Tr. 7722-23). Mr. Adelman devoted the same amount of time reviewing the record in the ESI patent case that he did to reviewing the record in the Upsher patent case. (32 Tr. 7724). He rendered an opinion on the strength of Schering's case against Upsher. 32 Tr. 7729. Tellingly, he rendered *none* about the ESI case. Mr. Miller's testimony about the strength of Schering's position in the ESI patent case thus stands unrefuted.

The reason Mr. Adelman did not render an opinion on the ESI case is apparent. The patented sustained release mechanism in K-Dur 20 consists of its coating. (SPF 3.418-3.421). The ingredients in the coating of ESI's product were identical to those described in the patent.

(SPF 3.487-3.488). To get around this fact, ESI rested its defense heavily on the contentions 1) that the patent required the ingredients in the coating to be mixed, and 2) that the ingredients in the ESI product's coating were not mixed. (SPF 3.472, 3.476, 3.479-3.482, 3.495-3.496). But it turned out that, contrary to ESI's contention, the ingredients in its product's coating *were* mixed. Indeed, Mr. Miller's opinion rested in significant part on scientific experiments performed on ESI's coating by Dr. Langer, which proved that the materials in ESI's product's coating *were* mixed. (13 Tr. 2822, 2932).[20] Dr. Langer performed *four* experiments on the coating in ESI's product, each of which *independently* showed that the materials in ESI's coating were mixed at the intermolecular level. (13 Tr. 2822, 2932). These tests devastated ESI's defense in the patent case. *See* Findings 3.516-3.562.

Complaint Counsel called Dr. Banakar to rebut the testimony of Dr. Langer. However, Dr. Banakar was able to criticize only *one* of the *four* tests on which Dr. Langer relied. (26 Tr. 6439). This left three unrefuted scientific tests, each showing that the materials in ESI's coating were mixed at the intermolecular level. Under these circumstances, Mr. Adelman could not have rendered an opinion rebutting Mr. Miller.

Thus, the unrefuted evidence shows that, if the ESI case had gone to trial, it is almost certain that ESI's product would have been enjoined from entering the market until September 2006. Under these circumstances, the settlement permitting ESI's product to enter the market in January 2004 is procompetitive. (*See* 6 Tr. at 1211-12).

ARGUMENT

There Was No Proof That The ESI Settlement Had An Anticompetitive Effect

Complaint Counsel introduced no evidence that the *particular settlement* in the ESI case reached an anticompetitive outcome. All of their arguments – which are briefly identified in the

---

[20] Mr. Miller also pointed out that the patent did not require mixing. (SPF 3.509-3.510).

next three paragraphs – depend on the proposition that *all* settlements that set an entry date and involve a net payment are anticompetitive. It is Schering's position that in this, the first case of its kind, Complaint Counsel had to prove that *this particular* settlement reached an anticompetitive outcome. Complaint Counsel have failed to do so.

1. Complaint Counsel argue that the court-supervised ESI settlement is *per se* unlawful. But a new *per se* rule is impossible to justify in this case. (a) Such a rule would run counter to the strong public policy encouraging settlements – especially court supervised settlements. (b) Patent-shortening settlements – i.e., those providing for entry before patent expiration – have clear redeeming virtue. And (c) neither the courts nor the Commission have any prior experience with patent-shortening settlements. A new *per se* rule should not be created in the first case of its type, *especially* where Complaint Counsel failed to prove that *this* settlement reached an anticompetitive outcome.

2. A quick look approach is unwarranted for these same reasons. Complaint Counsel's argument for quick look treatment rests on economic theory alone. It has no empirical underpinning. And the facts in *this* case strongly suggest that the settlement achieved through court supervision resulted in as much, or more, competition than any available alternative.

3. Complaint Counsel argue that they have *proved*, under the rule of reason, that the ESI settlement had an anticompetitive effect. But this argument is little more than a repackaging of their *per se* argument. Complaint Counsel's proof against the ESI settlement consisted almost entirely of Professor Bresnahan's opinion testimony that, in the case of *any* settlement with a net payment, "we can be certain that the settlement contract delivers less competition than would litigating." (6 Tr. 1130)(SPF 3.226).

The assumptions underlying the theory have no empirical support. Indeed, Professor Bresnahan had to concede that the opinion does not stand up, even as a matter of theory, once the nearly ubiquitous phenomenon of risk aversion is taken into consideration. Thus, he conceded:

"a risk averse patent holder is willing to settle for an entry date that is *earlier* than the expected date under litigation in order to gain certainty." (6 Tr. 1153-54).[21]

We respond to Complaint Counsel's three arguments at greater length below.

A. A New *Per Se* Rule Cannot Be Justified

There is "a presumption in favor of a rule-of-reason standard" in analyzing restraints of trade. *Business Elec. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 726 (1988). (*See* ID 96). This presumption avoids the "potential costs … that would result from mislabeling procompetitive activities as per se unlawful." *Seagood Trading Corp. v. Jerrico, Inc.*, 924 F.2d 1555, 1567 (11th Cir. 1991).

Courts may depart from the rule of reason only "after they have had sufficient experience with a particular type of restraint to know that it is manifestly anticompetitive." (ID 96 *citing Broadcast Music, Inc. v. Columbia Broad. Sys., Inc*., 441 U.S. 1, 9 (1979); *see also* ID 96-100). That experience also must result in a judicial conviction that the practice "lack[s] … any redeeming virtue." (ID 96, 99, *citing Continental T.V. Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 50 (1977)). *See NYNEX Corp. v. Discon, Inc.*, 525 U.S. 128, 133 (1998).

The Commission has brought two previous cases involving agreements relating to patent litigation, neither of which involved a patent-shortening settlement, or indeed any settlement.[22] Even in these cases, recognizing the newness of its initiative into this area, the Commission cautioned: "each case must be examined with respect to its *particular facts.*" Statement of Chairman Robert Pitofsky, *et al., In re Abbott Labs. and Geneva Pharms., Inc.* (accompanying order and decision at p. 1)(emphasis added). The Commission was especially careful not to condemn final settlements. *Compare Abbott* Decision and Order Paragraph II-III (forbidding

---

21 *See* discussion of risk aversion as it affects a party's settlement decisions in Richard A. Posner, *Economic Analysis of Law*, 337-38 (1973).

22 *In re Abbott Labs. and Geneva Pharms., Inc.*, No. G-3946, 2000 FTC LEXIS 66 (May 22, 2000), and *In re Hoechst Marion Rousel, Inc.*, No. 9293, 2001 FTC LEXIS 56 (May 8, 2001). In both cases, the patent holder allegedly paid the generic to stay off the market during the course of the patent litigation, which continued.

outright certain types of agreements not involving final settlements) *with* Paragraph IV (providing only for notice of similar agreements involving final settlements).

Patent-shortening settlements are particularly ill suited to *per se* condemnation because they have considerable "redeeming virtue." (ID 99, *quoting Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976); *see also* ID at 100; SPF 3.361-3.368). First of all, settlements replace risk with certainty, permitting businesses to plan and allocate resources in an efficiency-enhancing manner.[23] Second, settlements are absolutely essential to the functioning of our judicial system. And third, settlements save the parties legal fees and other intangible costs resulting from distraction of executives and others in the lawsuit.[24] As a result, the competitive analysis "must balance '*deeply instilled policy of settlement[s]*' against claims that patent settlement unreasonably restrained trade" (ID at 99 (emphasis added), *citing Speed Shore Corp. v. Denda*, 605 F.2d 469, 473 (9th Cir. 1979)).

In *Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163, 171 (1931), the Supreme Court considered the settlement of conflicting patent claims, under which three oil companies cross-licensed their patents and shared the royalties from competing products. Outside the settlement context, the Court surely would have condemned this arrangement summarily. But because the agreements settled *bona fide* patent disputes, the Court rejected *per se* treatment. *See also Boston Scientific Corp. v. Schneider (Eur.) AG*, 983 F. Supp. 245, 270-71 (D. Mass. 1997) (rejecting claim that a settlement agreement was anticompetitive *because of* "general rule that settlements and cross-licensing agreements do not, without something more, violate the antitrust laws").[25]

---

23 *See* testimony of mediation and negotiation expert William O'Shaughnessy at 29 Tr. 7066. *See also* SPF 3.361-3.368.

24 As Mr. O'Shaughnessy stated, "… for every dollar spent in R&D, about 27 cents is spent in patent litigation. … What I do know is that if you get rid of settlements, that 27 cents goes up and the dollar goes down. There's less money available for innovation and more money gets sucked into the litigation process. So, for this economy to work well, settlements are essential, especially patent settlements." (29 Tr. 7108; *see also* 29 Tr. 7065-66, 7073-74).

25 None of the cases cited by Complaint Counsel suggests that courts would summarily condemn a final settlement of a *bona fide* patent dispute that shortens the patent life. *Masonite*, *Singer*, *Line Material*, and *New Wrinkle* stand for the proposition that a settlement may be *per se* unlawful when it reaches an anticompetitive outcome which

Second, *patent-shortening* settlements have an additional redeeming virtue. They permit the alleged infringer to enter the market prior to the expiration of the patent. Complaint Counsel repeatedly state, as though it were proven fact, that the ESI settlement "delayed" entry of ESI's generic. It can as easily be said that the ESI settlement *accelerated* ESI's entry to a date sooner than patent expiration. Quite obviously, whether the settlement delayed entry or accelerated entry depends upon who would have won the patent case.

Complaint Counsel analogize Schering's settlements to horizontal market divisions, which *are* subject to *per se* treatment. But this analogy does not apply to a settlement of a patent suit.[26] (*See* ID 97-98). This is so because, if the patentee had won the suit, the alleged infringer would be excluded from the market altogether. Indeed, this analogy does not square with Complaint Counsel's concession, (Complaint Counsel's Trial Brief at 43), that a settlement setting a date of entry without more is not unlawful. Such a settlement is clearly a market division.

Courts have been deferential to settlements even where the settlement agreement would normally be a *per se* violation of the antitrust laws. As Professor Hovenkamp explained, some such settlements "would be illegal *per se* if created in the absence of a genuine intellectual property dispute." Hovenkamp, *Antitrust Law*, ¶ 2046 at 262. "Nevertheless," according to Hovenkamp, "assuming a genuine dispute, the outcome of even a settlement agreement

---

would not have resulted from the patentee's winning the lawsuit. (ID 100). In *United States v. Masonite Corp.*, 316 U.S. 265, 282-83 (1942), the Supreme Court condemned a settlement under which the patentee licensed the alleged infringer and the parties put in place a system of fixing resale prices of the patented product. The Supreme Court held that such a price fixing arrangement was outside the patent grant. *See also United States v. New Wrinkle, Inc.*, 342 U.S. 371, 374 (1952)(industry-wide patent "settlement" condemned only after defendants admitted the settlement was entered into "to establish minimum prices throughout the industry"); and *United States v. Line Material Co.*, 333 U.S. 287, 310-12 (1948)(after award in interference proceeding, patentees in same field cross-licensed patents and fixed sale prices of devices utilizing both patents; price-fixing held outside patent grant and subject to the Sherman Act). *See also United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963)(conspiracy to enforce patents against Japanese competitors unlawful; aggregating competing patents in hands of Singer went "beyond the limits of the patent monopoly");

[26] As now-Chairman Muris cautioned: "lawyers will be tempted to reason primarily from analogy, not evidence. This temptation must be resisted." Muris, *The Rule of Reason After California Dental*, 68 Antitrust L.J. 527, 539 (2000).

producing a *per se* antitrust violation might be no more anticompetitive than the outcome of litigation. A judgment establishing the validity of a rival's claim might [leave the rival] with a monopoly." *Id.* at 263. "Given these factors, the courts have responded by being fairly generous to settlements …." *Id.* "As a result, some agreements that would be unlawful if undertaken in the absence of a reasonable dispute may be lawful when used to settle a bona fide dispute." *Id.* at 265. *See Clorox Co. v. Sterling Winthrop, Inc.*, 117 F.3d 50 (2d Cir. 1997) (discussed by Hovenkamp, *supra* at 264-65). *See also United States v. Westinghouse Elec. Corp.*, 648 F.2d 642, 649 (9th Cir. 1981); *Carter v. Variflex, Inc.*, 101 F. Supp. 2d 1261, 1265-66 (C.D. Cal. 2000); *United States v. Studiengesellschaft Kohle m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir 1981).

The *Cardizem* and *Terazosin* district court opinions are not to the contrary. As the ALJ observed, these cases did not involve patent-shortening settlements or settlements at all. (ID 97). In each case, the brand name paid a generic entrant millions of dollars a month or a quarter to stay off the market while the patent litigation was pending. Both district courts emphasized that these agreements did not settle the litigation or relieve any burden on the courts. *In re Cardizem CD Antitrust Litig.* 105 F. Supp. 2d 682, 705 (E.D. Mich. 2000) ("The $10 million quarterly payments also created the incentive to pursue the litigation beyond the district court and through the appellate courts by extending those interim payments until entry of a final and unappealable order or judgment."); *In re Terazosin Hydrochloride Antitrust Litig.* 164 F. Supp. 2d 1340, 1350 (S.D. Fla. 2000) ("Abbott's confidential agreement with Geneva did not resolve its action before the Northern District of Illinois; in fact, it tended to prolong that dispute to Abbott's advantage."). Even more important, neither agreement shortened the patent life of the brand name company's patent. No redeeming virtues resulted: no settlement and no shortening of the patent life.[27]

---

[27] Complaint Counsel claim that the *Cardizem* settlement did shorten the patent life and guaranteed generic entry before patent expiration. (CAB 43 n.40). But Complaint Counsel are mistaken. In *Cardizem*, the brand name company did give the generic an *option* on a license to enter the market after eighteen months. But to exercise the option the generic had to 1) give up the $10 million quarterly payments that the brand name was paying it to stay off the market; and it had to 2) pay upfront fees and running royalties. *See In re Cardizem*, 105 F. Supp. 2d at 697-98,

Moreover, in *In re Tamoxifen Citrate Antitrust Litigation*, 2002 U.S. Dist. LEXIS 17211 (E.D.N.Y. Aug. 26, 2002), a federal court in New York ruled recently that the lawfulness of a patent settlement which included a net payment necessarily depended on the merits of the patent case – a holding inconsistent with Complaint Counsel's *per se* rule.

B. An Abbreviated Approach Is Not Justified

An antitrust tribunal may entertain a quick look analysis only when "an observer with even a rudimentary understanding of economics could conclude that the arrangemen[t] . . . would have an anticompetitive effect" *and* where "the great likelihood of anticompetitive effects can easily be ascertained." (ID 101, quoting *California Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999)). The anticompetitive effect cannot merely be theoretical or presumed: the court must "consider[] whether the effects actually are anticompetitive." *Id.* at 775 n.12; *see* Timothy J. Muris, *California Dental Association v. FTC: The Revenge of Footnote 17*, 8 S. Ct. Econ. Rev. 265, 310 (2000)("*CDA* should be read to require all plaintiffs to have an empirical basis for why the restraint harms consumers").

Courts simply will not apply quick look where there are plausible competing claims about the effects of an arrangement (such as the "redeeming virtues" of a patent-shortening settlement). *See California Dental*, 526 U.S. at 778. *See also Bogan v. Hodgkins*, 166 F.3d 509, 514 (2d Cir. 1999) (quick look inappropriate given "sound allegations of procompetitive benefit"); *Continental Airlines, Inc. v. United Airlines, Inc.*, 277 F.3d 499, 514 (4th Cir. 2002). Thus, quick look "would [n]ever suffice" when, as here, final settlements of *bona fide* patent disputes "come with the imprimatur of [*Standard Oil*] describing the potential virtues of such arrangements." *U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 595 (1st Cir. 1993); *see Carter v. Variflex, Inc.*, 101 F. Supp. 2d 1261, 1266 (C.D. Cal. 2000) (restrictive field of use

---

705. It was not likely that the generic would exercise the option, and the District Court held that the option did not affect the analysis. *Id.* at 705.

provisions in settlement and supracompetitive prices for patented products not "the kind of drastic effect on price or output that would warrant application of a quick look analysis").

Nor does the "inherently suspect" formulation of *Massachusetts Board of Registration in Optometry*, 110 F.T.C. 549, 604 (1988), change the analysis. To be inherently suspect, "a persuasive explanation of how the restraint will lead to an anticompetitive effect is necessary. More complex 'stories' are likely to be more appropriately evaluated under a full rule of reason." Timothy J. Muris, *The FTC and the Rule of Reason: In Defense of Massachusetts Board*, 66 Antitrust L.J. 773, 803 (1998).

C. Complaint Counsel Have Not Proved Anticompetitive Effects

Complaint Counsel state in their brief that the distinction between *per se* analysis and rule of reason analysis is "irrelevant." CAB at 40. Hardly. Under the rule of reason, Complaint Counsel must *prove* that the ESI settlement had an anticompetitive effect, and they did not do so. (ID 102 and cases cited therein).

Evidence of anticompetitive intent is not enough. *Nynex Corp. v. Discon, Inc.*, 525 U.S. at 135 (rejecting use of anticompetitive intent to recast defendants' conduct as *per se* unlawful, holding: "plaintiff here must allege and prove harm … to competition itself"); *SCFC ILC, Inc. v. Visa USA, Inc.*, 36 F.3d 958, 970 (10th Cir. 1994) (evidence of intent "may reveal a mental state but is not an objective basis upon which section 1 liability may be found"); *Deauville Corp. v. Federated Dep't Stores, Inc.*, 756 F.2d 1183, 1192 (5th Cir. 1985) ("An evil intent alone is insufficient to establish a violation under the rule of reason").[28]

Complaint Counsel represented to Judge Chappell that they would meet their burden by proving that the settlement involved "payment for delay."

> THE COURT: … are you saying the Government has to prove the payment was for delay in order to win this case?

---

[28] Anticompetitive intent, standing alone, is also insufficient to establish improper maintenance of monopoly power. *See, e.g., United States v. Microsoft Corp*., 253 F.3d 34, 59 (D.C. Cir.), *cert. denied*, 122 S. Ct. 350 (2001); *Olympia Equipment Leasing Co. v. Western Union Telegraph Co*., 797 F. 2d 370, 379 (7th Cir. 1986); *see also Brooke Group Ltd. v. Brown & Williamson Tobacco Corp*., 509 U.S. 209, 225 (1993).

> [COMPLAINT COUNSEL]: Absolutely. That's what we will prove at trial.[29]

Complaint Counsel further explained to the Court that they could prove payment for delay in one of two ways: either by proving (1) that there would have been a different settlement with an earlier entry date if no money had been paid; or (2) that the entry date in the settlement that *was* reached was later than the expected entry date under litigation. July 25, 2001 Tr. 31.[30] Complaint Counsel have proven neither.

1. No Proof of an Alternate Settlement

In an effort to prove that there would have been an alternate settlement with an earlier entry date if no money had been paid, Complaint Counsel have relied on testimony at an investigational hearing by Michael Dey, an ESI official involved in the settlement negotiations. Mr. Dey had stated in response to a question by Complaint Counsel that "*if* Schering had been willing to allow [ESI] onto the market before 2004," ESI "*may have*" been willing to settle for less money. (4 Tr. 632-33 (quoting Dey I.H.))(SPF 3.227). But neither Complaint Counsel nor Professor Bresnahan offered any affirmative evidence that ESI actually *would have* settled for less money and an earlier entry date. More importantly, Complaint Counsel's own evidence showed that Schering was completely unwilling to settle on any entry date earlier than January 1, 2004, no matter what other terms were in the agreement. (SPF 2.57). Complaint Counsel, thus, suffered a failure of proof on their contention that there would have been a settlement with an earlier entry date if no money had been paid. (*See* ID 112).

2. Professor Bresnahan's Model

Complaint Counsel's only effort to prove that the settlement delivered less competition than litigation consisted of Professor Bresnahan's testimony. He had little to say about the

---

[29] July 25, 2001 Tr. 34 (ID 106).

[30] Thus, Complaint Counsel explained that it was possible "that Schering obtained a later entry date than it would have if they had settled the case without a payment"; and he explained that it was possible that Schering "obtained a later date than it expected to obtain through litigation." July 25, 2001 Tr. 31.

particular settlement reached in the ESI case. Instead, he testified that in his opinion *all* settlements that include a net payment "will deliver less competition than would litigating." (6 Tr. 1130)(SPF 3.226). Thus, his testimony amounts to little more than a repackaging of Complaint Counsel's position that any net payment makes the settlement of a patent case *per se* illegal.

Moreover, so far as the record in this case reflects, Professor Bresnahan is the only economist who holds this opinion. Several reputable economists disagree with it. (6 Tr. 1131-32)(SPF 3.224). For example, Richard J. Gilbert expressly disagreed in an article written about this and other cases, stating "[t]he fact that the settlement involves a payment from the patentee to the challenger is *not* sufficient to determine that the settlement is anticompetitive."[31] Mr. Gilbert points out that "these cases are not as simple as they appear," (SPF 3.225), and states that it is relevant, *inter alia*, whether the settlement has been "subjected to judicial review," and whether "the size of the payment from the patentee" "is a large fraction of the monopoly profits from the patented drug." (Gilbert, 69 Antitrust L.J. at 76, 78)(SPX 836).[32]

Similarly, Schering's economists have demonstrated that as a matter of economic theory, one would expect to find many settlements that are procompetitive, and that are made possible only by payments. (24 Tr. 5681-82, 5778-81; 25 Tr. 6166; 29 Tr. 7182)(SPF 3.229-3.237, 3.241, 3.278, 3.286-3.290). And Professor Bresnahan has admitted that once risk aversion is taken into account, his model does not work. Thus, he conceded that "a risk averse patent holder is willing to settle for an entry date that is earlier than the expected date under litigation in order to obtain certainty." (6 Tr. 1153-54). Professor (now Chief Judge) Richard Posner treats risk aversion as one of the three major factors likely to influence settlement decisions. Posner, *Economic Analysis of Law*, 337-38.

---

31 *See* n.4, *supra*.

32 The amount of the payment here, $15 million, even if one values the bet at $10 million, is about 2 percent of the $606 million in profits Schering anticipated from K-Dur sales from the date of the settlement until January 1, 2004, when ESI's product could enter the market under the agreement. (SPF 2.97).

Risk aversion and the desire for certainty are nearly ubiquitous in the business world. As Nobel laureate Paul Samuelson explained: "People are generally risk-averse, preferring a sure thing to uncertain levels of consumption…." (SPF 3.243; *see also* observations of Nobel laureate Kenneth Arrow at SPF 3.244). As a result, the risk averse "model has by and large replaced the risk neutral economic man as economists' 'canonical' model of individual choice behavior."[33] Risk aversion also underlies the decision-making of most corporate managers. (29 Tr. 7172). As Professor Scherer observed, "[o]nly the decision maker who attaches no significance whatsoever to avoiding risk will always choose alternatives with the highest best-guess payoffs. And such managers, empirical studies suggest, are rare." (SPF 3.245; *see also* SPF 3.246-48). Professor Bresnahan conceded that business managers are rarely risk-neutral, preferring a sure thing to uncertainty. (SPF 3.249).[34] And this is true of Schering, too. (SPF 3.257, 3.258, 3.261, 3.264-3.266).

Complaint Counsel asserts that a party "will settle only if settlement terms provide as much profit as [that] party expects to earn if the litigation proceeded to conclusion." (CAB at 57). But risk aversion theory says otherwise. A party may settle for considerably less than the probablistic value of the litigation in order to achieve certainty. Risk aversion theory teaches that, in the context of a patent-shortening settlement, most companies would be willing to pay some amount to achieve an entry date which reflected the probable outcome of the litigation. (*See* SPF 3.227, 3.235, 3.281-3.284).

When confronted by respondent's experts' models with the many circumstances in which a payment might be necessary to achieve a settlement, and in which the settlement should as a

---

33 *See* Oliver Williamson, cited at SR-CPF 1268, noting that the assumption of risk neutrality was "patently counterfactual."

34 Professor Bresnahan's model will only work if one makes a number of assumptions, risk neutrality being one. But an expert's model is only valid if its underlying assumptions are shown to be true. *E.g., Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1056-57 (8th Cir. 1999)(expert testimony unprobative because "[n]ot all relevant circumstances were incorporated into the expert's method of analysis related to antitrust liability"), *cert. denied*, 531 U.S. 979 (2000); *American Booksellers Ass'n v. Barnes & Noble, Inc.*, 135 F. Supp.2d 1031, 1041-42 (N.D. Cal. 2001) ("too many assumptions and simplifications that are not supported by real-world evidence"). Complaint Counsel argues that Schering has the burden to *disprove* Professor Bresnahan's assumptions. But that is not the law.

matter of economic theory provide earlier entry than litigation, Complaint Counsel make a significant concession. Complaint Counsel concede that "these models lay out limited conditions under which there are settlements that parties prefer to litigation and that provide *more* competition than is expected under litigation…." (CAB at 68). Complaint Counsel argue, however, that there is always going to be an anticompetitive settlement involving a larger payment and a later entry date, and that given the economic incentives, the parties will always choose the anticompetitive settlement.[35]

The problem with this argument is that it does not apply to the ESI settlement. The evidence strongly suggests that Schering did not want to pay "more money for a later date." Schering advised Judge Rueter of its antitrust concerns and desire to go to trial, and repeatedly declined to consider payment to ESI. The evidence tends to show that, at Judge Rueter's urging, Schering paid the minimum amount necessary to achieve settlement. The evidence tends to show that this minimum payment was agreed to by Schering only after the entry date had been agreed to. And there is not a shred of evidence that the settlement provided less competition than litigation.

Most people prefer to obey the law – either for reasons of morality or because the consequences of violating the law are costly and acutely unpleasant. (SPF 3.321-3.323, SR-CPF 1152, 1178). The evidence in this case would support a finding that the Schering officials wanted to steer a wide berth around any antitrust violation.

3. Relevance of the Merits of the Patent Case

The ESI settlement provided for entry of ESI's generic 30 months *earlier* than the expiration of the K-Dur 20 patent, and some time later than would have been possible if ESI had

---

35 Thus, Complaint Counsel write, at p. 68 of their Appeal Brief:

> For any procompetitive settlement (as defined by the models), there are a multitude of anticompetitive settlements that the parties prefer. Each theory is, therefore, a road map to anticompetitive conduct: if parties can pay for an entry date, the incumbent will pay more money for a later date.

won the patent case. The question of whether the ESI settlement *delayed* entry as Complaint Counsel claim, or *accelerated* entry, quite obviously turns on who would have won the patent case. Thus, speaking for himself, Commissioner Thomas B. Leary has observed:

> [T]he ultimate competitive impact of a pharmaceutical patent settlement is really dependent on the merits of the underlying patent litigation.

Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II*, Speech Before the ABA's Antitrust Health Care Program (May 17, 2001) at 1 ("Leary II").[36]

We do not understand Complaint Counsel to dispute the proposition that they must compare the competition delivered by the settlement with the competition that would have resulted from litigating. Both Complaint Counsel and their expert recognize the relevance of this comparison by claiming repeatedly that the ESI settlement delivers less competition "than would litigating."[37] Professor Bresnahan flatly agreed that a settlement is procompetitive if the percentage probability that the brand name company would have won the patent case is larger than the percentage of the remaining patent life during which the generic agreed [under the settlement] to stay off the market. (6 Tr. 1211-12.)

Complaint Counsel's position is, instead, that the Commission and the Courts should not try to address the merits of the patent case because it is too difficult to do. (*See* CAB 2, 17, 45). It is on *this* point that the parties disagree.

The disagreement is thus not over the question *whether* the competition delivered by the settlement must be compared to the competition which would have resulted from litigation. The disagreement is over how that comparison is to be made. Complaint Counsel would have the

---

[36] Commissioner Leary then explores whether there is some proxy for actually exploring the patent merits, *e.g.*, whether a payment is a sure-fire marker for a settlement which is worse for consumers than litigation. We believe we have shown above that a payment is *not* such a sure-fire marker.

[37] *E.g.*, Bresnahan testimony at 6 Tr. 1130 (settlement with a payment delivers less competition "than would litigating").

comparison made by economists, who would try to find proxies[38] for addressing the patent case directly: they would presumably have to look at the size of any payment, calibrate the parties' risk aversion, asymmetric information, the effect of the cash-strapped position of the generic, the likely effects of third party entry, time value of money, anticipated growth or shrinkage of the market and so forth. Schering believes it is more sensible to examine the patent merits directly.[39]

It is wrong to say that it is impossible to address the merits of the underlying patent case.[40] District courts, which have no special expertise in patent issues, adjudicate patent cases all the time. In the context of preliminary injunction motions, they address the issue of "*likelihood* of success on the merits" in patent cases. The Intellectual Property Guidelines *require* that the Commission address whether it is reasonably probable that a product is not blocked from the market by a patent. *See Antitrust Guidelines for the Licensing of Intellectual Property ("Intellectual Property Guidelines")*, § 5.5, Example 5 (addressing potential competitor issue). And courts routinely compare the *likely* outcome of litigation to the relief obtained in a settlement in ruling on the fairness of class action settlements. *See infra* at 69.

(a) Complaint Counsel Had To Show That Schering Did Not Have The Patent Holder's Right To Exclude ESI

Under the patent law, Schering has the right to exclude ESI from making, using or selling a product utilizing Schering's valid patented invention, 35 U.S.C. §§ 154, 271(a) (2000). *United States v. United Shoe Mach. Co.*, 247 U.S. 32, 57 (1917)("[A patent's] strength is in the restraint,

---

38 *See* Leary II at 4, exploring the question whether there is a "proxy test" which would avoid "a burdensome fact-specific inquiry into issues of validity and infringement."

39 Complaint Counsel's economic approach has another deficiency. Under Complaint Counsel's approach, the economist tries to infer the parties' *expectations* about the likely outcome of the litigation. But the antitrust laws are not concerned with expectations or intentions of the parties. They are concerned with effects. *See supra* at 51-53, 60-61. Effects can be assessed only by an objective evaluation of the evidence on validity and infringement.

40 As Professor Willig explained, "it's like saying I can't do the right analysis, so I'll embrace the wrong and dangerous analysis. That would be absolutely not the right way to go for policy." (29 Tr. 7234)(SPF 3.315).

the right to exclude others from the use of the invention, absolutely or on the terms the patentee chooses to impose.") The antitrust laws fully accommodate this statutory right. *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964)("The patent laws … are in *pari materia* with the antitrust laws and modify them *pro tanto.*"); *Intellectual Property Guidelines*, §§ 1.0, 2.1, 3.1. (*See* ID 82-84). This principle was recently upheld by a district court considering the settlement of another Hatch-Waxman patent litigation. The court stated: "[t]he holder of a lawfully obtained patent … may 'prevent other[s] from utilizing his discovery'…. In light of these basic principles, plaintiffs must prove that [defendant's] conduct (i.e. entering into the Settlement Agreement) was impermissible under the patent laws." *Tamoxifen Citrate Antitrust Litig.*, 2002 U.S. Dist. LEXIS 17211, at *15-*16. Thus, "it appears beyond doubt that a court [ruling on the antitrust claims] will have to determine the validity, enforceability or scope of [defendant's] patent." *Id.* at *20.

If Schering's patents afforded it the *lawful* right to block Upsher and ESI entry, the exercise of that right in whole or in part could not harm competition. *See NYNEX Corp. v. Discon, Inc.*, 525 U.S. 128, 136 (1998)("We concede Discon's claim that the petitioners' behavior hurt consumers …. But that consumer injury naturally flowed … from the exercise of market power that is *lawfully* in the hands of a monopolist….."). Thus, under the teachings of *Discon*, unless Complaint Counsel show that Schering's patent is invalid or ESI did not infringe, Schering's settlements are a *lawful* exercise of its exclusionary power. But Complaint Counsel made no such showing. (ID at 103). In fact, the evidence shows just the opposite. (SPF 3.387-3.682).

The implications of this failure of proof are well illustrated by *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256 (3d Cir. 1998). In *West Penn*, the court rejected an antitrust challenge to an agreement between two utilities providing that one of them, Allegheny, withdraw its application to the state utilities commission to become a competitor to the other. One key to the decision was plaintiff's failure to allege that, absent the agreement, the commission would have approved Allegheny's application. It was not enough that plaintiff "would have benefited

from competition." *Id*. at 267. Similarly, it is not enough that consumers might have benefited if ESI prevailed in the litigation. Complaint Counsel did not prove that ESI would have prevailed.

In *West Penn*, the agreement was not condemned even though there was presumably some probability that Allegheny's application would have been granted. An allegation and proof that the application *would have* been granted were required. Here, there was neither an allegation nor proof that Schering lacked the patent rights lawfully to block ESI's product from the market.

Apparently recognizing their problem, Complaint Counsel have argued that the patent law provides no right to exclude, only a right to invoke the state's power to exclude. (CAB 44). But the argument is not correct. There is no requirement to go to court prior to exercising rights to exclude or restrict granted by a patent. Complaint Counsel have conceded that a patent holder may settle a case with an agreement to compromise an entry date without any decision by the court. *See supra*, at 1. Indeed, the holder of a valid and infringed patent may grant licenses that are "restricted in point of space or time, … [so long as he does] not enlarge his monopoly." *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 456 (1940). No prior judicial permission is required.

If there were merit to Complaint Counsel's theory, courts would have held that a patent owner must obtain a declaratory judgment or other judicial relief before exercising any patent rights. Contrary to *Guidelines* Example 5, a firm would be a likely potential entrant until the patent holder had invoked the power of the courts. Contrary to *Guidelines* Example 10, pooling of blocking patents would be unlawful unless a court has already ruled the patents were actually blocking.

(b) Complaint Counsel Had, At A Minimum, To Prove That The Settlement Was Unfair To Consumers

Even if Complaint Counsel are not required to prove that ESI would have won the underlying patent case, they had at a minimum to prove that the entry date under the settlement was not a fair reflection of the merits of the patent case.

It is central to Complaint Counsel's position in this matter that settlements of patent litigation often affect consumers who are parties neither to the case nor the settlement agreement. Complaint Counsel point out that it is important that settlements be fair not only to the parties but also to consumers. We agree with this point. Indeed, Schering's inside antitrust counsel made this precise point to Judge Rueter. (15 Tr**.** 2613). And this point explains why the issues presented in these cases are important to the Commission.

This problem of settlements that may affect people who are not parties to the case being settled is not an unfamiliar one. Settlement of class actions affect not only the parties and the lawyers for the class. They also affect absent class members. For that reason, class action settlements require Court approval after a "fairness" hearing at which counsel for the absent class members may appear and be heard. Courts approve the settlement only if it is fair to the absent class members.

A fairness review necessarily includes a comparison of the proposed settlement with the "likely rewards of litigation." *See, e.g., Polar Int'l Brokerage Corp. v. Reeve*, 187 F.R.D. 108, 112 (S.D.N.Y. 1999) ("the court 'need[s] to compare the terms of the compromise with the likely rewards of litigation'") (citations omitted); *Van Horn v. Trickey*, 840 F.2d 604, 607 (8th Cir. 1988) (comparing strength of plaintiff's case against terms of proposed settlements is "[t]he single most important factor in determining whether a settlement is fair, reasonable, and adequate"); *Petruzzi's, Inc. v. Darling-Delaware Co.*, 880 F. Supp. 292, 296 (M.D. Pa. 1995) ("court must independently and *objectively* analyze the evidence and circumstances before it in

order to determine whether the settlement is in the best interest of [class members]")(emphasis added).

Thus, courts are perfectly capable of comparing settlements with the likely outcome of litigations. But Complaint Counsel made no effort to address the merits of the patent case or to compare the settlement to the likely outcome of that case. There is no basis in the record for a finding that the settlement provides less competition than would litigating.

Instead, Complaint Counsel ask this Commission to condemn a settlement 1) reached through court supervised mediation, 2) involving a small payment, 3) which Judge Rueter apparently thought necessary to reach a settlement, 4) *and* which was better for consumers than continued litigation, because Schering would almost certainly have prevailed.

It was incumbent on Complaint Counsel to do more.

D. The ESI Settlement Could Have Had No Effect On Competition In Any Event

The Complaint alleges clearly and repeatedly that ESI's generic version of K-Dur 20 was blocked from the market until March 2002 by the 180-day exclusivity rights given to Upsher by the Hatch-Waxman Act. (Complaint ¶¶ 15, 29, 42, 60, 66.) ESI announced its exit from the entire oral generic business in July 2001. (SPF 3.343.) The settlement agreement thus had no impact on ESI at all. Its generic version of K-Dur 20 would never have come to market no matter what the resolution of the litigation.

Complaint Counsel's response is that the Commission should ignore ESI's exit because it was a "subsequent event." (CAB 62). This argument is inconsistent with the Commission's *Antitrust Guidelines for Collaborations Among Competitors* (FTC and DOJ, April 2000) ("*Collaboration Guidelines*"). In Section 2.4, the Commission states it assesses "competitive effects of a relevant agreement as of the time of possible harm to competition." The Commission further elaborates in Example 3 of the *Collaboration Guidelines*, where "circumstances … have changed over time, … the evaluating Agency would determine whether the [agreement] now harms competition." Just like Example 3, the Commission must determine

whether the ESI settlement harms competition now or at some other time of possible harm. *See also Virginia Vermiculite, Ltd. v W.R. Grace & Co.*, 98 F. Supp. 2d 729, 739 (W.D. Va. 2000)(expert's prediction of future anticompetitive effects not reliable where he failed to account for possible intervening events); *Seagood Trading Corp. v. Jerrico, Inc.*, 924 F.2d 1555, 1570-73 (11th Cir.1991); *Three Movies of Tarzana v. Pacific Theatres, Inc.*, 828 F.2d 1395, 1400 (9th Cir. 1987).

Upsher's 180-day exclusivity rights and the exit of ESI were the event that prevented ESI's entry, not the settlement. It is, thus, plain that the ESI settlement does not injure competition.[41]

E. Monopoly Power

Complaint Counsel undertook the burden of establishing that Schering's K-Dur 20 had monopoly power at the time of the settlement agreements. Their expert, Professor Bresnahan applied a monopoly power screen as part of his expert opinion. According to him, if K-Dur 20 did not have monopoly power, the settlement agreements were not anticompetitive. He used this monopoly screen both for the Section 1 and the Section 2 claims. (SPF 3.1-3.2).

Complaint Counsel failed to prove that K-Dur 20 had monopoly power. (ID 115-119). The evidence showed that K-Dur 20 is a sustained-release potassium chloride supplement. (SPF 3.11). The potassium chloride market was a "crowded market" in 1997 and 1998. (SPF 3.40). There were over twenty such products competing in that market, some of which were low-priced generics. (IDF 33-37)(SPF 3.13-3.18). Internal Schering documents show that Schering viewed the low-priced generics as its most formidable competition. (IDF 60-63)(SPF 3.40-3.45).

---

[41] The Complaint alleges that the ESI settlement agreement not only prohibits ESI from marketing the precise product at issue in the lawsuit, until January 1, 2004, but also applies to other products. *See* Compl. ¶ 55. Obviously, the parties did not want to be back in court litigating similar but not identical products. (CX 1492 at 159:9-160:2 (Dey I.H.)) (SPF 2.97). The provision of the settlement agreement is thus a reasonable ancillary restraint so long as the settlement is otherwise lawful. (SPF 2.98-2.99). Both Professor Bresnahan and Complaint Counsel concede this. (*See* 5 Tr. 987-88, 990-91)(SPF 2.99); Compl. Counsel's Opp'n to Upsher-Smith's Mot. To Dismiss at p. 7 n.20.

All of the competing products were "therapeutically equivalent." (IDF 38-48)(SPF 3.19-3.27). K-Dur 20, to be sure, was the only potassium chloride supplement in a 20 mEq tablet form. But there were many 10 mEq products, and a consumer could take two 10 mEq capsules to achieve the same therapeutic benefit provided in one 20 mEq horse tablet. (IDF 45)(SPF 3.24-3.25). The products were clearly substitutable one for another.

K-Dur 20 was the market leader, with a market share of from 35% to 40% by unit volume. (IDF 400-404)(SPF 3.118-3.120). It was one of the higher-priced products in the category, but not the highest. (IDF 111)(SPF 3.169, 3.199-3.203). Schering's marketplace success stemmed from the fact that it spent more promoting K-Dur 20 than the rest of the category combined. **(***See* IDF 79-80)(SPF 3.88-3.43).

Faced with incontrovertible evidence of a broad market, Complaint Counsel attempt to salvage their monopolization case by suggesting that they can rely on rising prices, sales growth, and the effect of mandatory substitution laws as "direct" evidence of monopoly power. (CAB at 20-21, 72-75; see id. at 46-53 (arguing evidence shows "substantial market power").

Increasing prices without more is not evidence of monopoly power. *See, e.g., Forsyth v. Humana, Inc.*, 114 F.3d 1467, 1475-76 (9th Cir. 1997), *aff'd on other grounds*, 525 U.S. 299 (1999); *Blue Cross & Blue Shield United v. Marshfield Clinic*, 65 F.3d 1406, 1412 (7th Cir. 1995). *See also SMS Sys. Maint. Servs., Inc. v. Digital Equip. Corp.*, 188 F.3d 11, 17 (1st Cir. 1999)("In any market with some degree of product differentiation, goods of a single brand will enjoy a certain degree of uniqueness. . . that fact, without more, does not suffice to establish that the manufacturer enjoys monopoly power in that market."), *cert. denied*, 528 U.S. 1188 (2000).

Likewise, sales *growth* is not a symptom of monopoly power. The exercise of monopoly power is coincident with the power to *limit* output, not expand output through advertising and promotion as here. *Stearns Airport Equip. Co. v. FMC Corp.*, 170 F.3d 518, 524-26 (5th Cir. 1999)(aggressive product promotion resulting in sales gains not unlawful maintenance of monopoly power).

Complaint Counsel's main point, however, is that K-Dur 20 knew it would lose and did lose significant sales to the Upsher product, Klor-Con 20, when Klor-Con 20 came on the market. But this is in no way evidence of monopoly power. It is a result of the unique laws and regulations related to generic substitution. Klor-Con 20 obtained an "AB" rating to K-Dur 20, by establishing that it was bio-equivalent to K-Dur 20. An "AB" rated generic in the prescription pharmaceutical market has a unique ability to take share away from the pioneer drug to which it is AB rated, *whether or not that pioneer drug had monopoly power*. **(***See* ID 118)(SPF 3.179-3.187). In fact, every brand name drug, whether patented or not, will lose significant sales to a generic which gets on the market not by going through the expensive New Drug process at FDA, but by proving "bioequivalence to the brand" and achieving an "AB" rating.

The reasons for this are as follows. In the prescription drug marketplace, prescribing doctors are the ones who decide which company's drug will be purchased by their patients. Pharmaceutical manufacturers promote their drugs to these prescribing physicians. The money they spend to invest in their brand is spent with doctors as the target audience. (SPF 3.92).

But there is one exception to the rule that the doctor decides which drug will be purchased. Under mandatory generic substitution laws, pharmacists may, and often must, dispense the AB rated generic when the physician prescribes the brand. (SPF 3.181). So when Schering persuades hundreds of thousands of doctors—through its marketing efforts—to choose K-Dur 20, the pharmacists will sell Klor-Con 20 to the patient. (SPF 3.182-3.187).

The generic drug free-rides on the brand name's R&D to obtain approval, and free-rides on the brand name's promotional efforts to make the sale. The generic's cost structure is different and it charges a lower price. (SPF 3.188-3.189).

This loss of sales will be suffered mainly by the brand name drug to which the generic is AB-rated. And it will happen no matter how competitive the category was immediately before

the generic enters. It is not proof of monopoly power.[42] Moreover, the entry of Klor-Con M20 did not constrain K-Dur 20's price—just the opposite. When Klor-Con M20 entered the market, Schering planned to terminate its rebates and giveaways, leading to an increase in K-Dur 20's price. (SR-CPF 1115).[43]

Schering joins in Upsher's more lengthy discussion of this issue.

CONCLUSION

For all the above stated reasons, the Commission should dismiss Complaint Counsel's case challenging the ESI settlement.

Respectfully submitted,

_____

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

Attorneys for Respondent
Schering-Plough Corporation

Of Counsel:

Jonathan A. Wasserman
Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

Dated: September 30, 2002

---

[42] This is especially so in connection with the ESI settlement. By the time ESI's product could enter the market, there was already an AB rated generic available: Upsher's Klor-Con 20.

[43] This is consistent with the findings in the economic studies cited by Complaint Counsel. (CAB 48 n. 44, 46, 47). Each of these studies concludes that the price of brand-name products rises after generic entry.

CERTIFICATE OF SERVICE

I hereby certify that this 7th day of October 2002, I caused an original, twelve paper copies, and an electronic copy of the Appeal Brief of Respondent Schering-Plough Corporation, Public Version, to be filed with the Secretary of the Commission;

And that one 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

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

_____

Diane E. Bieri