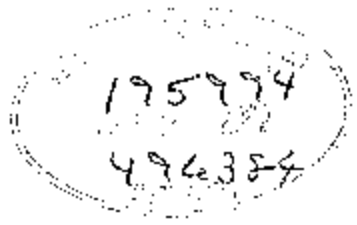
ORIGINAL



UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

DOCKET NO. 9297

IN THE MATTER OF

SCHERING-PLOUGH CORPORATION,

UPSHER-SMITH LABORATORIES, INC.,

and

AMERICAN HOME PRODUCTS CORPORATION

REPLY BRIEF OF COUNSEL SUPPORTING THE COMPLAINT

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October 24, 2002

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TABLE OF ABBREVIATIONS

The following abbreviations and citation forms are used:

CAB -	Appeal Brief of Counsel Supporting the Complaint, filed August 6, 2002
CPF -	Complaint Counsel's Proposed Findings of Fact, filed April 15, 2002
CPRF-S -	Complaint Counsel's Reply to Schering's Proposed Findings of Fact, filed April 26, 2002
CPRF-U -	Complaint Counsel's Reply to Upsher's Proposed Findings of Fact, filed April 26, 2002
CPTB -	Complaint Counsel's Brief in Support of Proposed Findings of Fact and Conclusions of Law, filed April 15, 2002
CPTRB -	Complaint Counsel's Reply Brief, filed April 26, 2002
CX -	Complaint counsel exhibit
GPA -	Brief of *Amicus Curiae* The Generic Pharmaceutical Association, filed September 30, 2002
ID -	Initial Decision
IDF -	Initial Decision Finding of Fact
SAB -	Appeal Brief of the Respondent Schering-Plough Corporation, filed September 30, 2002
SPTB-E -	Respondent Schering-Plough Corporation's Corrected Brief in Support of its Proposed Findings of Fact and Conclusions of Law Regarding the ESI Settlement, filed April 18, 2002
SPTB-U -	Respondent Schering-Plough Corporation's Corrected Brief in Support of its Proposed Findings of Fact and Conclusions of Law Regarding the Upsher-Smith Settlement, filed April 18, 2002
SPTRB -	Respondent Schering-Plough Corporation's Reply Brief in Support of its Proposed Findings of Fact and Conclusions of Law, filed April 26, 2002
SPX -	Schering-Plough exhibit

UAB - Answering Brief of Upsher-Smith Laboratories, Inc., filed September 30, 2002

UPTB - Upsher-Smith's Post-Trial Brief, filed April 15, 2002, corrected April 18, 2002

UPTRB - Upsher-Smith's Post-Trial Rebuttal Brief, filed April 26, 2002, corrected May 1, 2002

USX - Upsher-Smith exhibit

WLF - Brief of Washington Legal Foundation as *Amicus Curiae* in Support of Respondents, filed September 30, 2002

Citations to the trial transcript include the volume, page number, and witness name: Tr. 34:8147 (Bresnahan).

Pages of exhibits are referenced by bates number: CX 459 at AHP0500190.

References to investigational hearing or deposition transcripts that have been included in the trial record as exhibits include the exhibit number, the transcript page(s), the witness name, and the designation "IH" or "dep": CX 1550 at 79 (Poorvin dep).

In camera documents, testimony, and findings are designated by the notation [in camera] following the citation: CPF 122 [in camera].

INTRODUCTION

In its answering brief, Schering concedes that it paid AHP $15 million in exchange for an agreed-upon entry date of 2004; and, although the parties deny it, the overwhelming evidence shows that Schering's $60 million payment to Upsher likewise included payment in exchange for an agreed-upon entry date of 2001. That evidence includes nearly all of the parties' contemporaneous documents, the agreement itself, and the parties' own admissions. Set against that, the parties can point to virtually nothing other than their own self-serving denials at trial, a redacted Board memorandum prepared in anticipation of legal scrutiny, and a sales forecast created *after* the $60 million and entry date had been agreed to. Indeed, with Schering having expressly offered AHP a payment to exit the same market only a few months *before* the Upsher agreement, and having paid AHP $15 million for an agreed-upon entry date only months *after* the Upsher agreement, it is hard to imagine a stronger evidentiary basis – short of an actual confession by the parties – for concluding that Schering paid Upsher for agreeing to the 2001 entry date.

Having vigorously denied that it ever would have compensated Upsher for the 2001 entry date, Schering insists in the next breath that there is nothing wrong if it did. But the parties' contemporaneous efforts to obscure the nature of their agreement provide a truer reflection of what they recognized as its likely competitive effect than all the post-hoc rationalizations of their experts. Indeed, the nature of the AHP and Upsher agreements is nothing new. Rather, they are a type with which the antitrust laws are exceedingly familiar: agreements between competitors that perpetuate monopoly profits and then provide a means for sharing them. None of the justifications raised by the parties to explain away their agreements – the uncertainty of competition, the settlement context, the assertion of patent rights – entitles competitors to agree

to perpetuate and share monopoly profits. No procompetitive justification has been shown in this case. To the contrary, the evidence conclusively establishes that the agreements delayed expected competition in a market where Schering exercised monopoly power, to the benefit of the parties but at great cost to consumers. The agreements accordingly should be held to violate Section 5 of the FTC Act.

I. The Commission's *De Novo* Review Owes No Deference to the ALJ's Legal Conclusions Based on Witness Credibility

Respondents argue that the Commission should give "great deference" to ALJ Chappell's conclusions that are based on witness credibility. SAB 36-37; UAB 32-36. Although the Commission "can . . . give some deference" to an ALJ's determinations of credibility, this policy is premised on the assumption that the ALJ "closely scrutinize[d] [the] witnesses' overall demeanor." *Trans Union Corp.*, 2000 FTC LEXIS 23 at *8-*9 (2002) (internal quotations omitted) (quoting *Horizon Corp.*, 97 F.T.C. 464, 857 n.77 (1981)). Such deference is unwarranted here.

First, even though ALJ Chappell uses the terms "credibility" and "credible," he made no findings of fact based on witness demeanor at trial. Instead, his "Conclusions of Law and Analysis" uses these terms as shorthand for "greater weight of the evidence." *See, e.g.*, ID 86 ("Without a proper market definition, Bresnahan's opinions [concerning Schering's monopoly power] are without proper foundation and lose credibility."). Second, even assuming that his credibility determinations actually touched on witness credibility, ALJ Chappell provides no particularized support for these determinations based on his observations of the trial witnesses. *See, e.g.*, *Certified Bldg. Prods. Inc.*, 83 F.T.C. 1004, 1029 (1973) (setting aside ALJ's credibility

findings because they were not supported "with any degree of particularity"). Third, as this chart shows, the ALJ copied verbatim much of the "Conclusions of Law and Analysis" portion of his Initial Decision (ID 81-119) – including the credibility determinations – from respondents' trial briefs, raising serious doubts about whether he actually considered the evidentiary record as a whole. Accordingly, the Commission should give no deference to ALJ Chappell's credibility determinations, and review the record *de novo*.[1]

Initial Decision	Respondents' Briefs
81 (¶2-3)	UPCL 1
84 (¶2)	UPTB 62 & n.6
86 (¶3)	UPTB 62-63
86 (¶4)	SPTB-U 66 ¶2
87 (¶5) - 88 (¶1)	UPTB 63-64
88 (¶3) - 89 (¶2)	UPTB 64-66
90 (¶1-2)	UPTRB 34-35
91 (¶1-3)	UPTRB 36-38
91 (¶4)	UPTB 68-69
92 (¶2-4)	UPTB 69-74
93 (¶1)	UPTB 76
93 (¶2-4)	UPTB 80-82
94 (¶1)	UPTB 82 ¶1
94 (¶2-5)	UPTB 84-86
95 (¶1)	UPTB 87
95 (¶2)	UPTB 89

Initial Decision	Respondents' Briefs
102 (¶1)	SPTB-U 63-64
106 (¶1)	UPTB 50
106 (¶2-3) - 107	UPTB 1-3
107 (¶2)	UPTB 3, 35
108 (¶1)	UPTB 3-4
108 (¶2-3)	UPTB 12-14
109 (¶4) - 110 (¶1)	UPTB 26-27
110 (¶2)	UPTB 29; SPTB-U 19
110 (¶3)	UPTB 30-31
111 (¶1-2)	UPTB 33-34
111 (¶3)	SPTB-B 9
112 (¶2)	UPTB 39
112 (¶4) - 113(¶1)	UPTB 111
113 (¶1-4)	UPTB 111-14
114 (¶1-4)	UPTB 114-17
115 (¶2-3)	SPTB-U 68-69

[1] 16 C.F.R. § 3.54(a) (2002) (The Commission "will, to the extent necessary or desirable, exercise all the powers which it could have exercised if it had made the initial decision."); *see also Trans Union Corp.*, at *8-*9; *accord Amrep Corp.*, 102 F.T.C. 1362, 1670 (1983) ("[T]he Commission, not the ALJ, has the ultimate responsibility for finding of facts.").

96 (¶2)	UPTB 36; SPTB-U 61-62
97 (¶3)	SPTRB 26
97 (¶4) - 98(¶1)	UPTB 37
98 (¶1)	SPTB-U 61-62
99 (¶3) - 100	UPTB 39; SPTB-U 62-63
101 (¶4) - 102(¶1)	SPTB-U 63

116 (¶3)	UPTRB 39-40 & n.19
117 (¶1-5)	UPTRB 41, 43-46
118 (¶1-4)	UPTRB 46-48
119 (¶1-3)	UPTB 120-22
119 (¶3-4)	UPTRB 52-53

Respondents cite no cases to the contrary. *Universal Camera Corp. v. NLRB*, cited by Upsher, deals only with how federal appellate courts should review administrative decisions. 340 U.S. 474, 476-91 (1951). Upsher ignores the Supreme Court's explicit caution in *FCC v. Allentown Broadcasting Corp.* against applying the *Universal Camera* framework to an administrative agency's review of its ALJs' decisions. 349 U.S. 358, 364 (1955). *Cinderella Career & Finishing Schools, Inc. v. FTC*, cited by Schering, simply holds that the Commission should review all significant portions of the factual record and not ignore the ALJ's initial decision without articulating some basis for doing so. 425 F.2d 583, 589 (D.C. Cir. 1970).

The Commission cases respondents cite also are inapplicable. In those cases, the ALJ plainly reviewed the entire record, as required by Commission Rule 3.51(c).[2] Here, as in *Adolph Coors Co.*, it is doubtful that ALJ Chappell based his initial decision upon a consideration of the whole record, because he "relied to an extraordinary degree upon [respondents'] proposed findings and conclusions of law," made findings of fact "based to a considerable extent on bits

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[2] 16 C.F.R. § 3.51(c) (2002). *See Horizon*, 97 F.T.C. at 857 (finding that "the record as a whole adequately supports most of the findings and conclusions entered by the ALJ"); *Southern States Distrib. Co.*, 83 F.T.C. 1126, 1169-73 (1973) (finding ALJ had considered all of the relevant record evidence on issue before making credibility judgment); *Diener's, Inc.*, 81 F.T.C. 945, 974-83 (1972) (finding respondents could point to no record evidence conflicting with ALJ's credibility judgment); *Lenox, Inc.*, 73 F.T.C. 578, 604 (1968) (finding witness's testimony consistent with record evidence).

and pieces of unsupported and self-serving testimony, much of which is contradicted by documentary evidence," and "simply ignored" much of the evidence relied upon by complaint counsel. 83 F.T.C. 32, 177 (1973). Consequently, the Commission should review the entire record *de novo*, and make its own findings of fact and conclusions of law.[3]

II. Schering Paid AHP Not to Compete Until 2004

Schering now concedes that it paid AHP $15 million for its agreement not to enter until 2004. *See* SAB 49-51. Strikingly, Schering's only point of contention appears to be its claim that $5 million was paid for the *litigation* contingency (that is, the risk that AHP would prevail in the patent suit), but up to $10 million was paid for the *FDA* contingency (that is, the risk that AHP would gain FDA approval for its product).[4] Accordingly, there is no factual dispute that Schering paid AHP for its agreement to the January 2004 entry date. The only remaining question, therefore, is whether Schering's $15 million payment to its potential competitor in exchange for an entry date six years later is anticompetitive. *See* SAB 64. We show that it was in Sections IV-VII.[5]

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[3] *De novo* review is particularly important since ALJ Chappell applied the wrong standard of proof. *See* Complaint Counsel's Motion for Leave to File an Appeal Brief Exceeding the Word Limit in the Commission's Rules of Practice (July 15, 2002).

[4] AHP would get the full $10 million if it obtained FDA approval by July 1999, and lesser amounts if approved thereafter. The agreement thus expressly tied the size of the payment to how soon AHP became a competitive threat. *See* CX 472; CPF 872.

[5] The agreement that Schering now concedes it made with AHP appears defensible only if *any* uncertainty regarding entry – litigation or otherwise – permits an incumbent to pay an entrant to stay off the market. For example, the agreement that Schering describes appears little different, and just as illegal, from one where AHP lacked only FDA approval; Schering agreed to pay AHP $10 million to stay out of the market until January 2004; and Schering thereafter agreed to supply AHP with product to be sold as a generic.

III. Schering Paid Upsher Not to Compete Until September 2001

Having conceded that it paid AHP $15 million in exchange for an agreed-upon entry date (on top of $15 million paid for licenses to AHP products), Schering still disputes that any portion of its $60 million payment to Upsher was for the parties' agreed-upon entry date. Schering makes that contention despite the fact that the AHP agreement was only months *after* the Upsher agreement, and that only months *before* the Upsher agreement, Schering had expressly offered to pay AHP to stay out of the market. CX 459 at AHP0500190 (AHP would receive compensation for K-Dur-20 sales "in exchange for which [AHP] would cease its efforts to gain FDA approval of its accused generic version of K-Dur").

Schering admits that Upsher *asked* to be paid "to make up for the income that [Upsher] had projected to earn from sales" of generic K-Dur 20 (CX 338 at SP1200270), just as AHP did; and Schering understood Upsher to be asking for a payment for delay. SAB 37-38. Schering also admits (actually, affirmatively avers) that its counsel opined a few months later that it would be " more reasonable" for Schering to pay a potential generic competitor based on "the amount of revenues that the entrant could be expected to earn if it entered the market." CX 1525 at 30-31(Rule dep). And it does not dispute that its payments to Upsher $60 million – match Schering's internal calculations of what Upsher was expected to earn in generic K-Dur 20 revenues from the time of the settlement until September 2001. CX 283.

Perhaps most telling of all, Schering admits that the $60 million figure was chosen *before Schering ever evaluated a single item in the Upsher portfolio*. CPF 242-43. Schering nevertheless asks the Commission to believe that, by some happy coincidence, the portfolio

review turned up an Upsher product, Niacor-SR, that just happened to be worth at least $60 million to Schering. Furthering this remarkable coincidence, the parties claim that this product was uniquely valuable to Schering, so that Upsher had no foregone opportunity costs from licensing it to Schering – not a single company had offered Upsher a dime up-front for the product, but it was so uniquely valuable to Schering that it could approve a $60 million payment without any of the usual due diligence associated with such licenses.[6] Indeed, according to the parties, Niacor-SR was such a singular opportunity that Schering could authorize paying $60 million – double the amount it had ever paid in non-contingent license fees – based on little more than a single forecast by a single employee prepared in the equivalent of a "little bit more" than a single day's work. CPF 423, 427.

What evidence do the parties point to in support of this explanation for the $60 million? They cannot point to the plain language of the parties' agreement, because it shows that some consideration was for the agreed-upon entry date. They cannot point to evidence showing that Schering had no incentive to enter into such an agreement, because the evidence is overwhelmingly the other way, as Schering tacitly admits. SAB 8. They cannot show that the licensing review was handled in the ordinary course of business, because it was not.[7] They cannot even show any evidence linking the one sales forecast that was done to the decision to pay

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[6] Unless the product was uniquely valuable to Schering, it would not create the "value" that the parties claim was used to bridge their differences in settlement. If Upsher would have gotten $60 million for Niacor-SR anyway, then Upsher got nothing from the settlement for its foregone K-Dur sales – compensation that Schering admits Upsher demanded. *See* SAB 38 (Upsher sought "to replace the cash flow [it] had hoped to receive from sales of generic K-Dur 20 had Upsher won the patent case").

[7] *Compare* CPF 486-580 (Schering's ordinary licensing practices) *with* CPF 417-55 (Niacor-SR).

$60 million and to make the payment guaranteed. Indeed, the only record evidence explaining the amount and structure of Schering's payments is consistent with payment for the agreed-upon entry date.

In the absence of concrete evidence, the parties principally try to change the subject, by criticizing our experts. Beyond that, the evidence they rely upon consists of:

- A redacted Board memorandum, from which key information has been withheld;
- A sales forecast showing what the product ostensibly might earn if it was ever approved, which it was not;
- Schering's interest in a different (and possibly better) sustained-release niacin product, for which it had refused to make *any* guaranteed payment only a month earlier;
- Forecasts regarding the ostensibly bright prospects for sustained-release niacin – forecasts which Schering expressly rejected; and finally,
- The self-serving, uncorroborated testimony of the parties' witnesses at trial.

As discussed in the pages that follow, this evidence does not come close to rebutting what the parties' contemporaneous documents and admissions plainly show: Schering paid Upsher in exchange for its agreement to the September 2001 entry date.[8]

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[8] Upsher "reserves its objection to the use" of investigational hearing testimony. UAB 22 n.2. The testimony at issue is statements by Schering's negotiators about Upsher's repeated demands to be paid for lost generic K-Dur 20 revenues. Upsher does not dispute that these transcripts are part of the administrative record, having been admitted as party admissions. Nor does it offer any reason why, as Schering's party admissions, this testimony cannot properly be used to prove what Schering bought with its $60 million. And, Upsher's objections about a lack of opportunity to conduct cross-examination are untenable, since Upsher had ample opportunity to do so during the administrative proceeding. 16 C.F.R. § 3.41(d) (2002); *see Richardson v. Perales*, 402 U.S. 389, 404-05 (1971) (rejecting party's hearsay objection where party failed to subpoena and cross-examine declarants during hearing).

A. Mr. Audibert's Sales Forecast Does Not Explain the $60 Million Guaranteed Payment

Although respondents do not contest that the $60 million Schering paid Upsher matches Schering's estimate of Upsher's lost sales of generic K-Dur 20, they nonetheless insist that they fortuitously found a product in Upsher's pipeline that was worth the same amount. As support, they focus almost exclusively on a sales forecast prepared by James Audibert – a mid-level Schering employee – which simply projects that Niacor-SR, if approved, might yield more than $200 million in net present value over ten years. Schering devotes a full seven pages to bolstering Mr. Audibert's qualifications and to what he purportedly did – in a "little bit more" than one day – to prepare his forecast. SAB 17-24.

The issue, though, is not Mr. Audibert's qualifications, nor the reliability of his Niacor-SR sales forecast.[9] Rather, it is whether a single forecast trumps the direct evidence linking Schering's $60 million payment to Upsher's generic K-Dur 20 entry date, and can establish, by itself, that the payment was entirely for Niacor-SR. It cannot do either, because a sales projection alone reveals little about the size of the non-contingent payment that Schering would have been expected to commit.

The testimony of Schering's managers demonstrates the limited utility of such a forecast: it is "a lot of guess work" (CX 1494 at 42-43 (Driscoll III)), depends heavily on assumptions, and is only "part of the economic profile of the [licensing] opportunity." CX 1550 at 79 (Poorvin

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[9] Mr. Audibert's sales forecast, however, rests on several flawed assumptions raising significant doubts about its reliability. See CPF 456-84A. In addition, his sales forecast departed from the detailed forecasting Schering normally conducts when considering a drug for in-licensing. *See* CPRF-S 1.283 (describing the eleven-step Niaspan sales forecast conducted by Schering).

dep). A forecast makes no adjustment for the various risks that exist in bringing a drug to market – e.g., that Niacor-SR would not be approved (which it wasn't)[10] – or that, if approved, would not live up to expectations.[11] Decisions on whether to license a product and how much to pay up-front, if anything, therefore, are necessarily based on "a lot of reasons" (CX 1515 at 106 (Lauda IH)) – a sales forecast being but "one of many considerations that are used." CX 1530 at 79 (Poorvin dep).

The evidence from Schering's comparable licensing transactions confirms that no relationship exists between a product's projected sales (economic value) and the size of the non-contingent payment.

	Economic Value (millions)	Non-Contingent Payment (millions)	Ratio
*****	*****	*****	13:1
*****	*****	*****	4:1
Upsher	$225-65	$60	4:1
*****	*****	*****	28:1
*****	*****	*****	13:1
*****	*****	*****	52:1
*****	*****	*****	36:1
*****	*****	*****	40:1
*****	*****	*****	161:1

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[10] As Upsher's expert said: "[M]ore than in most other industries, there is a substantial risk that any particular product in the pipeline at any time won't get into the market." Tr. 26:6316 (Kerr); *see also* CX 1550 at 128 (Poorvin dep) ("[E]verybody knows . . . that filing an NDA does not guarantee approval").

[11] *See* Tr. 19:4390 (Lauda) (agreeing that commercial success of some products falls well below pre-approval expectations).

Not surprisingly, Schering emphasizes the single transaction – the Centocor deal for Remicade – [redacted] But even this deal bears little similarity to the Niacor-SR transaction. First, by focusing only on Remicade's economic value (which is based on Schering's "lower range" sales estimate), Schering conveniently ignores Remicade's "upper range" annual sales figures – [redacted] Second, Schering believed Remicade was a "breakthrough" therapy (Tr. 19:4480 (Lauda)) for treatment of diseases [redacted] It was a drug which Schering considered to be a "half a billion plus type of product." CX 1516 at 9-10 (Lauda dep). In contrast, Niacor-SR was an old compound in a crowded market. CX 341 at SP120247; CPF 264-86. Third, Schering expected Remicade's [redacted]; nonetheless, it did extensive due diligence to assess the product's potential. [redacted]; CX 1516 at 13-17 (Lauda dep). In contrast, Upsher had not even submitted its FDA application for Niacor-SR, yet Schering did virtually no due diligence before guaranteeing $60 million.

Despite Remicade's potential as a "breakthrough" therapy and [redacted] Schering still protected against the drug's possible failure by structuring the bulk of the licensing compensation to Centocor [redacted] (compared to only 10-15% for Niacor-SR). [redacted]

[redacted] CPF [redacted] 326 [redacted] By tying payments to performance, Schering ensures that it receives something of value in return for its investment.

In contrast, if the $60 million non-contingent payment was for Niacor-SR, it would not only represent twice as much as Schering had ever paid in non-contingent fees, but also would stand out as a striking exception to Schering's standard licensing practice. Nearly all of Schering's payments to Upsher came up-front, no-strings attached. By so structuring the payments, Schering assumed the risk of product failure.[12] While Remicade's upside potential explains its $30 million non-contingent payment, Schering cannot explain its decision to pay double that *and* take all the risk for sustained-release niacin, a drug whose market opportunity was "narrowing even prior to its introduction." CX 558 at SP002720.

Thus, whatever the merits of Mr. Audibert's sales projections, his forecast does not explain Schering's $60 million payment to Upsher.

B. Schering's Board Memo Confirms That Schering Paid Upsher to Stay off the Market

The memorandum to Schering's Board seeking approval for that payment does. In that memo, Schering managers told the Board that the agreement's payment terms were dictated by Upsher's insistence on a "guaranteed income stream" to replace the revenues that Upsher expected to forgo by agreeing to stay off the market until 2001:

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[12] By trying to divert attention to "total investment" (SAB 27-30), Schering runs away from the critical distinction between contingent and non-contingent payments. But it doesn't take "much business sense to know that a preference would be to adjust payments for contingencies if one could." CX 1550 at 223 (Poorvin dep).

Payment Terms
In the course of our discussions with Upsher-Smith they indicated that a prerequisite of any deal would be to provide them with a guaranteed income stream for the next twenty-four months to make up for the income that they had projected to earn from sales of Klor Con had they been successful in their suit.

CX 338 at SP1200270. Notwithstanding this clear statement, Schering claims the memo shows that Schering's Board was told that the license opportunity "could only be approved if it was of sufficient value to Schering, separate and apart from the settlement," and that the Board therefore must have made that determination. SAB 24.

The memo says no such thing. Instead, the language on which Schering relies – a portion of a sentence that is partially redacted – merely recounts what Schering purportedly told Upsher during the negotiations. CX 338 at SP1200268 ("**REDACTED** . . . we informed them [Upsher] that any such deal should stand on its own merit independent of the settlement."). This thin reed simply cannot support the inference that respondents would have the Commission draw. Whether or not Schering would have been interested in Niacor-SR absent the settlement, this contemporaneous document shows that the deal's payment terms were designed to compensate Upsher for revenues it expected to lose by settling (and were not merely to satisfy some vague "desire for cash" on Upsher's part).

The testimony of two Schering Board members that their approval required them to assess the deal on its own, independent of the settlement (SAB 24-25), is simply not borne out by the memorandum on which Schering relies. In any event, the directors had neither the information nor expertise to conduct an independent assessment of Niacor-SR. CPF 220-21. They considered the licensing proposal for no more than twenty minutes. CPF 220. The directors understandably relied on senior management's recommendation – as they had always

done. CX 1526 at 33-34 (Russo, Patricia dep) (Board never rejected management's recommendation for a licensing agreement); CX 1500 at 41-42 (Garfield dep). In relying on senior management, Board members naturally expected that "all the necessary backup work was done by the responsible people reporting to the top management," without inquiring into the nature or extent of that backup work. CX 1528 at 20 (Schreyer dep); *see also* CPF 221, 383. But, they were never informed, for example, that Schering's European operation had already rejected the Niacor-SR licensing opportunity -- a fact at least one director thought "[w]e probably should have been aware of." CX 1485 at 33 (Becherer dep). Finally, they never saw the actual agreement, the terms of which link Schering's payment to Upsher's promise to stay off the market.

C. The Evidence Contradicts Schering's Statements That it Would Not Pay Upsher to Stay off the Market

It is undisputed that Upsher demanded a multi-million dollar payment to stay off the market. As Schering admits: "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." SAB 38. The dispute, therefore, is whether Schering acceded to that demand.

Schering claims it did not, relying primarily on testimony from its Associate General Counsel, John Hoffman, who purportedly told Upsher that "Schering was not going to be paying Upsher-Smith to stay off the market." Tr. 15:3540-41 (Hoffman). From this testimony, respondents ask the Commission to infer that Hoffman provided the same advice to his client and

that Schering complied. Having chosen to maintain their attorney-client privilege, however, respondents offered no evidence to link Hoffman's statements to Schering's behavior.

Not only has Schering failed to provide evidence to justify this inferential leap,[13] the evidence not shrouded by privilege shows the opposite. Schering already had decided that it would compensate a generic if the arrangement would keep its product off the market. Just a month before the Upsher settlement, Schering proposed to pay AHP to drop its generic product and instead promote K-Dur 20. CX 459 (AHP would receive compensation for K-Dur 20 sales "in exchange for which [AHP] would cease its efforts to gain FDA approval of its accused generic version of K-Dur"). Schering now concedes, despite testimony by Schering witnesses that it would not pay to keep AHP off the market,[14] that Schering, in fact, paid AHP $15 million for AHP's promise to stay off the market until 2004. SAB 49-50. And at least $10 million of that payment had nothing to do with the merits of the patent case; rather, it was tied solely to how soon AHP became a competitive threat. SAB 50-51; Tr. 12:2712 (Driscoll).

More telling than Mr. Hoffman's negotiating posture is the testimony of Schering's outside antitrust counsel, Rick Rule. During the AHP settlement negotiations, Mr. Rule told a federal magistrate judge that a payment from Schering to its potential generic competitor AHP would be "more defensible" if the payment were based on AHP's lost revenues rather than on a

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[13] Did Hoffman raise antitrust concerns with Upsher to get Upsher to lower its $80 million demand for payments, or because he had so advised his client? Did Hoffman tell his business people about the antitrust risks of entering into settlement involving payments to a potential competitor? Did the Schering and Upsher business people actually listen to and follow their lawyer's legal advice, assuming they were so advised? We'll never know because respondents have claimed privilege for the best evidence of what was said and done inside Schering and Upsher.

[14] *See* Tr. 12:2631-32 (Hoffman); CX 1494 at 109 (Driscoll IH).

share of Schering's profits. Tr. 11:2584 (Rule). Calculating a payment based on "the amount of revenues that the entrant could expect to earn if it entered the market" (CX 1525 at 30-31 (Rule dep)) is precisely what Schering did regarding Upsher. CX 283 at SP018781 (calculating net present value of Upsher's lost generic K-Dur 20 sales).

D. Respondents' Other Arguments

1. Upsher's attempt to find a European licensing partner

The supposed interest of several companies in a European license for Niacor-SR does nothing to further respondents' claim that the entire $60 million payment was for Niacor-SR. Prior to licensing Niacor-SR to Schering, Upsher shopped the European rights to "virtually everybody who is a pharmaceutical manufacturer" outside of the United States. Tr. 28:6931 (Kerr). Over 40 firms – including one of Schering's European subsidiaries – either did not bother to respond or rejected the opportunity out of hand, citing Niacor SR's "limited market volume and the known side effects" (CX 849); "doubtful . . . commercial prospects" (CX 857); "limited commercial potential" (CX 859); and "low tolerability" and "risk of [liver toxicity]." CX 856; *see also* CPF 786-94, 799-801.

Respondents do not contest these facts. (Upsher details its failed attempts to license Niacor-SR in Europe in contemporaneous business documents. CPF 786-806). Faced with this overwhelmingly negative reaction, respondents point to the modicum of interest shown by the five remaining companies. But this evidence further undermines respondents' position:

- Each of these supposedly interested companies expressed concerns about Niacor-SR's side effects or limited market potential. One company concluded – based on its review of the same data seen by Mr. Audibert – that Niacor-SR "had a toxicity

profile that suggested that it was not going to be a successful drug." Tr. 33:7886 (Egan);[15]

- They insisted on more time to conduct due diligence of the licensing opportunity;[16]

- Three of the companies eventually rejected the Niacor-SR licensing proposal, citing, for example, the "extreme[] difficul[ty]" in introducing Niacor-SR to market (CX 869);

- Most importantly, none of the supposedly interested companies offered any payment at all to Upsher. Indeed, the one firm singled out by Upsher as the "most interested" (UPF 416) objected to "high up-front and milestone payments." USX 598 at USL13188.

2. Niacor-SR and Niaspan sales forecasts

As a basis for Upsher's claim that the $60 million was entirely for Niacor-SR, Upsher relies on testimony from its senior executives about Niacor-SR's supposedly huge sales potential. UAB 6; *see, e.g.*, Tr. 20:4831 (Dritsas) (expecting Niacor-SR to generate annual sales of at least $100 million, and up to $250 million). Upsher also points to stock analyst projections of $250 million in annual sales for Kos's Niaspan as corroboration for its internal estimates. UAB 7-8; Tr. 21:5025-26 (Kralovec). Upsher's contemporaneous Niacor-SR forecasts belie Upsher's trial

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[15] *See also* CX 883 at USL11808 (expressing "concern over the elevation in the liver function tests").

[16] *See, e.g.*, CX 868 at USL11812 (three separate groups to review Niacor-SR for at least six weeks before deciding whether to proceed); CX 880 at USL11827 ("expert physician [to] review the clinical data" before a "go/no go decision").

claims. Five separate Upsher projections estimate Niacor-SR's annual sales to peak at $25 million – a fraction of the $250 million Upsher trumpeted at trial.

	Peak Sales Projected	Exhibit
April 1996	$25 million	CX 321 at USL05248
September 1996	$20 million	CX 322 at USL05287
October 1996	$3.3 million	CX 234 at USL12785
July 1997	$7.5 million	CX 930 at USL13191
September 1997	$11.5 million	CX 1094 at USL11935

And, despite the analysts' lofty estimates for Niaspan,[17] Upsher halved its own expectations for Niacor-SR in the year leading up to the Niaspan launch.

Retreating from the far lower forecasts found in their own contemporaneous records,[18] Upsher executives claimed these forecasts were based on the assumption that Upsher would not have a sales force. *See, e.g.*, Tr. 23:5527-28 (Troup). To the contrary, the forecast prepared just two weeks after the Schering/Upsher agreement, for example, is based on the explicit assumption that Upsher "will hire or retain a detail force to market Niacor-SR successfully." CX 930 at USL13192.

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[17] Even Schering found the analysts' Niaspan projections to be inflated: "Although certain investment firms have publicly stated that 'Niaspan is a $250 million product,' we don't necessarily share that view." CX 558 at SP002719 (estimating "peak sales for Niaspan" at only "134 million").

[18] Ignoring the contemporaneous documents cited above, Upsher points only to a lone outdated March *1994* document (USX 1563) to support its inflated Niacor-SR projections.

3. Schering's interest in sustained-release niacin

Respondents contend that Schering's negotiations with Kos for Niaspan demonstrates Schering's genuine interest in Niacor-SR. SAB 40; UAB 8-9. While Schering's interest in Niacor-SR might explain its willingness to pay something for a license,[19] it does not explain why it paid $60 million in non-contingent payments for one. Schering's refusal to commit anything up-front for Niaspan – a sustained-release niacin product which respondents concede is at least as good as Niacor-SR – proves that Schering did not.

Schering's experience with Niaspan tells even more: Schering had serious questions about whether sustained-release niacin could succeed -- questions that went unanswered during its Niaspan review. Schering's Niaspan team leader documented that far more had to be understood – including patent status, regulatory labeling, manufacturing capabilities, and product liability – "before a deal could be made" for a sustained-release niacin product. CX 546 at SP002770. Schering's expert medical panel warned that "niacin and, particularly, sustained-release niacin, has . . . [a] bad reputation among primary care physicians," and that Niaspan had failed to overcome the "liver toxicity" and the "side effect" problems responsible for this negative perception. CX 576 at SP02715, 02717. And ultimately, Schering's Vice-President of Sales and Marketing concluded that "Niaspan does not represent a large-enough opportunity in the marketplace" to justify "distraction from [Schering's] core businesses." CX 558 at SP002719. From this record, it is simply not credible that Schering committed to pay Upsher

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[19] Dr. Levy testified that the terms of the Niacor-SR license agreement were unremarkable in all respects save one: the huge, non-contingent payment. Tr. 7:1336-37. Thus, Upsher's remaining arguments – that it invested millions in developing Niacor-SR and that doctors "encouraged" it to do so (UAB 5-6) – are irrelevant, as they go only to a point not in dispute – that Upsher's project to develop Niacor-SR was genuine.

$60 million for a different (and possibly worse) sustained-release niacin product just eight days later – without consulting any of its principals involved in reviewing Niaspan.

E. The Terms of the Agreement Show Payment for the Entry Date

The terms of the agreement are clear and unambiguous. Respondents' effort to disregard these terms, and "change the writing of the agreement"[20] is contrary to law.[21]

1. Paragraph 11

Paragraph 11 of the agreement requires Schering to pay Upsher $60 million "in consideration for the licenses, rights, and obligations described in paragraphs 1 through 10"; Paragraph 3 obligates Upsher to "not market in the United States its Klor Con M20 potassium chloride product . . . prior to September 1, 2001." CX 348 at USL03186-88. The agreement's unambiguous language thus directly links Schering's $60 million payment with Upsher's promise to stay off the K-Dur 20 market.

Respondents nevertheless proclaim that Schering's $60 million payment has nothing to do with Upsher's agreed-to entry date. Respondents offer their version of the "intended" meaning of Paragraph 11, and argue that the ALJ rightly ignored the agreement's unambiguous language. But in their effort to retreat from the agreement's explicit terms, respondents concede that Paragraph 11 identifies the consideration for Schering's payment. UAB 28; SAB 41.

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[20] *Halper v. Halper*, 164 F.3d 830, 840-41 (3d Cir. 1999).

[21] *See City of Orange Township v. Empire Mortgage Servs., Inc.*, 775 A.2d 174, 179 (N.J. Super. Ct. App. Div. 2001) ("[W]here the terms of a contract are clear and unambiguous there is no room for interpretation or construction and the courts must enforce those terms as written."). The Third Circuit, in *Halper v. Halper*, cited by Schering, held that under New Jersey contract law, extrinsic evidence cannot be used for the "purpose of changing the writing" of the contract, but "only for the purpose of interpreting the writing." 164 F.3d at 841. Upsher's case holds likewise. *Atl. N. Airlines, Inc. v. Schwimmer*, 96 A.2d 652, 656 (N.J. 1953).

Consideration is not merely "boilerplate language." UAB 28. Rather, it is the "bargained-for-exchange" of a contract that gives the parties the legal right to enforce the promises made in return.[22] By specifically identifying Upsher's promise not to compete as consideration for Schering's payments, the agreement creates specific contractual rights for breach that would not exist if the only consideration for Schering's payments in Paragraph 11 were the product licenses (Paragraphs 7-10).[23] If the parties had intended that Upsher's agreement to stay off the market would be consideration only for the settlement and not for the $60 million, then their experienced licensing counsel could have drafted terms to reflect this supposed intent.

Despite the plain language of Paragraph 11, however, respondents would have the Commission find that the payment was not for the entry date because it is termed a royalty. What matters, however, is the payment's purpose, not its name.[24] Schering was willing to make a $60 million "royalty" payment only on the condition that Upsher would agree to stay off the market until September 1, 2001. This is what the contract says, and it means that some portion of the payment (whether called a royalty or not) was for the entry date. Moreover, the extrinsic

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[22] *Corbin on Contracts* § 5.1 (2001); *accord Shebar v. Sanyo Bus. Sys. Corp.*, 544 A.2d 377, 383 (N.J. 1988).

[23] *See Rothman Realty Corp. v. MacLain*, 84 A.2d 482, 484 (N.J. Super. Ct. Ch. Div. 1951) (explaining significance of apportioning consideration to distinct portions of the contract).

[24] *See In re Yarn Processing Patent Validity Litig.*, 541 F.2d 1127, 1135-37 (5th Cir. 1977) (holding that contract provision – despite its "royalty" label – had "effectively fixed the price" of the product and was therefore *per se* illegal); *see also Basic Iron Ore Co. v. Dahlke*, 152 A. 73, 1930 N.J. LEXIS 517 at *5-6 (N.J. 1930) (holding that use of the term "royalties" is not determinative of contract's legal meaning).

evidence about the negotiations is entirely consistent with the contract's plain meaning. CPF 199-202, 212-18, 225-37, 240-44.

2. Paragraphs 3 and 12

Read together, Paragraphs 3 and 12 also link Schering's obligation to pay with Upsher's agreement to stay off the market. Respondents do not dispute this, but instead encourage the Commission to consider these paragraphs in isolation. SAB 43; CAB 29. These provisions are, however, parts of the same contract and further demonstrate that some of the $60 million was in return for Upsher's entry date.

Even if the contract is divided, the connection between the payment and the entry date is clear. Paragraph 3 provides that if the "Detailed Agreement" is declared invalid, Upsher can bring its generic K-Dur 20 to market. CX 348 at USL03186. Declaring the "Detailed Agreement" invalid would end Schering's obligation to make the $60 million payments. CPF 179. Therefore, whether read as a whole or as separate parts, the agreement directly ties Schering's payment obligations to Upsher's agreement not to enter.

F. Complaint Counsel's Experts Rendered Sound Opinion Testimony

Respondents' attempt to ignore the documentary evidence is obvious in their attacks on the analyses performed by Professor Bresnahan, our economic expert, and Dr. Levy, our pharmaceutical licensing expert.

1. Professor Timothy Bresnahan

Relying on well-established economic principles that he applied to the evidentiary record, Professor Bresnahan concluded that respondents acted consistently with their incentives and reached an agreement to delay entry. Respondents do not challenge the economic underpinnings of Professor Bresnahan's "revealed preference" and "market" tests. Rather, their criticism is that Professor Bresnahan does not agree with respondents' interpretation of the facts. As to the revealed preference test, Schering faults Professor Bresnahan's comparison of the Niaspan opportunity to that of Niacor-SR, because Niaspan was a co-promote, not a straight license. SAB 14-15. When asked by a Commissioner's office for transactions "similar" to Niacor-SR, however, Schering readily identified as "analogous" a co-promote for an entirely different drug. CX 1363 at FTC0001401 (Tequin). Apparently, a co-promote agreement is a bad comparison to Niacor-SR only when the result is unfavorable to respondents.

As to the "market test," respondents do not dispute that no other company offered Upsher anything for Niacor-SR, but merely assert the evidence should be ignored because Schering may value a licensing opportunity differently from the rest of the pharmaceutical world. SAB 16. Generally that may be true, but it is implausible to conclude that Schering valued Niacor-SR to be worth $60 million in up-front payments, while ***every other company*** that looked at this opportunity did not offer a dime. *See* Tr. 23:5593 (Troup).

Finally, respondents contest Professor Bresnahan's reliance on the parties' "incentives" to enter into an agreement whereby one party pays the other to delay its market entry. UAB 19-20; SAB 8. Economic incentives that show anticompetitive conduct is profitable and possible are relevant in analyzing the parties' actions. *See In re High Fructose Corn Syrup Antitrust Litig.*,

295 F.3d 651, 655 (7th Cir. 2002). Professor Bresnahan did not limit his analysis to the parties' incentives. Rather, he identified those incentives, then relied on evidence that the parties acted on them to conclude that Schering paid Upsher to accept an entry date. This is precisely the analysis an economic expert should provide in an antitrust case.

2. Dr. Nelson Levy

Based on more than two decades of broad experience in the pharmaceutical industry and comprehensive review of the factual record, Dr. Levy concluded that Schering's claim that it guaranteed $60 million for Niacor-SR is inconsistent with industry practice and Schering's own licensing and evaluation processes. Respondents try to pick apart his opinion, but each effort either distorts it or misstates the evidence.

Respondents challenge Dr. Levy's qualifications (UAB 14), but he doesn't need to be a cardiologist or lipidologist to know that Schering's Niacor-SR transaction deviates so strikingly from industry standards and Schering's own licensing practices – an opinion Dr. Levy was well-qualified to make. *See* CPRF-S 1.932 (detailing Dr. Levy's relevant credentials). Upsher claims Dr. Levy "rejects" net present value analysis. UAB 12. On the contrary, Dr. Levy testified that NPV is "very useful" in certain circumstances, but not in trying to value an unapproved product, like Niacor-SR, because the two critical variables in the analysis – cash flow and risk – are unknown. Tr. 10:2155-57 (Levy).[25] Upsher faults Dr. Levy for not valuing the other products

[25] *See* CX 1494 at 42-43 (Driscoll III) (forecasting "potential commercial performance of a product" is "very difficult"). Respondents attack on Dr. Levy's view of NPV takes nerve considering right before trial, they withdrew an expert who shared these same views. Tr. 1:83 (Pre-Hearing Conference).

Upsher licensed to Schering (UAB 11-13), but Schering likewise never valued them before guaranteeing the $60 million. CPF 312.

Schering challenges Dr. Levy's concern that Niacor-SR might have been toxic to the liver (SAB 26-27), but Schering's own expert medical panel found that practitioners "avoid" using niacin for cholesterol management "because of diminished efficacy and concern regarding liver toxicity." CX 576 at SP020709. Schering criticizes Dr. Levy's opinion that the Niacor-SR due diligence process was so cursory and inadequate that it fell immeasurably below both Schering's and industry standards (SAB 33-34), but concedes that it did [redacted] than ever before, while guaranteeing more money up-front than ever before. [redacted][26] Finally, respondents fault Dr. Levy for ignoring the impact of Kos's stock price decline on the parties' decision to abandon the Niacor-SR project. SAB 30-32; UAB 15. Dr. Levy did not ignore the impact – there was none. Upsher had already put Niacor-SR on hold, and decided to proceed with only "minimal activity" one month ***before*** Kos's stock price dropped in November 1997. CX 963 at USL12581; *see also* CPF 695.

IV. Payments For an Entry Date Are Inherently Anticompetitive

Respondents shun modern antitrust analysis. Rather than analyze the economic nature of the challenged restraints, they argue about the doctrinal box in which the restraints belong. They never directly respond to our contention that paying a potential competitor to accept an entry date is a payment not to compete and presumptively anticompetitive. Upsher ignores the issue; Schering collapses it into the question whether the agreements are *per se* illegal, suggesting that

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[26] *Compare* CPF 378-416 (industry due diligence) *and* CPF 485-580 (Schering's due diligence on other licensing deals) *with* CPF 417-45 (Schering's Niacor-SR review).

once any justification is proffered, absolute proof of anticompetitive effects is required. A restraint, however, may be presumptively anticompetitive without being illegal *per se*. *NCAA v. Bd. of Regents*, 468 U.S. 85 (1984); *see also Polk Bros., Inc. v. Forest City Enters., Inc.*, 776 F.2d 185, 189 (7th Cir. 1985) (requiring justification for a covenant not to compete).

A restraint is presumptively anticompetitive if "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect." *CDA v. FTC*, 526 U.S. 756, 770 (1999). It is a basic principle of industrial organization that when firms do not compete and agree to share the profits, they can earn more than they could by competing. This is precisely what Schering, Upsher, and AHP did.

Schering argues that if the challenged settlements are presumptively anticompetitive, then so too would be a patent split without a payment. This is a straw man; a patent split without compensation has a fundamentally different effect on competition. Market allocation, price-fixing, and payments not to compete are anticompetitive because they enable competitors to share the profits created by not competing. A settlement that splits the patent life without compensation provides no mechanism for the entrant to share the incumbent's profits. The entrant's only benefit is the right to compete, and the negotiated entry date should directly reflect the merits of the litigation. Only when the entrant is compensated for that date does the agreement provide a means for competitors to create and then share monopoly profits.

The settlement in *Clorox*, for example, was not presumptively anticompetitive because nothing in it created monopoly profits or a mechanism for sharing them. The parties had strong incentives to protect their ability to compete with one another, and the settlement presumably

reflected the parties' assessment of the strengths of their respective positions in the underlying trademark litigation. *Clorox Co. v. Sterling Winthrop*, 117 F.3d 50, 55-56, 60-61 (2d Cir. 1997).

Schering accepts that under *United States v. Masonite Corp.*, 316 U.S. 265, 279 (1942), a patent settlement in which the parties fixed prices would be presumptively anticompetitive. SAB 56 n.25. It is left, therefore, trying to distinguish price-fixing from payments not to compete. But agreements that allow competitors to share the benefits of not competing – regardless of their form – are anticompetitive. *Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 65 F.3d 1406, 1415 (7th Cir. 1995) ("It would be a strange interpretation of antitrust law that forbade competitors to agree on what price to charge, thus eliminating price competition among them, but allowed them to divide markets, thus eliminating all competition among them."). In *Masonite*, moreover, the Supreme Court analyzed the substance of the agreements – sharing monopoly profits to induce potential competitors not to compete. Had Masonite used sales agents that were not potential competitors, the agreements would likely have been acceptable; Masonite's problems arose when it turned potential competitors into allies that shared Masonite's profits. 316 U.S. at 279-80. The *Cardizem* court also saw no difference between the payment not to market a generic and price-fixing, finding that the agreement "allowed HMRI to maintain or fix the price of Cardizem CD at a non-competitive level during the life of the agreement." *In re Cardizem CD Litig.*, 105 F. Supp. 2d 682, 706 (E.D. Mich. 2000), *appeal docketed*, No. 00-2483 (6th Cir. Dec. 19, 2000).

Cardizem and *Terazosin* cannot be meaningfully distinguished on the ground that they were not final litigation settlements. The *Terazosin* court found both the Geneva interim agreement and the Zenith final settlement to be presumptively anticompetitive. *In re Terazosin*

Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340, 1348-49, 1351 (S.D. Fla. 2000). A final settlement involving a payment not to enter, moreover, could be more dangerous to competition than an interim settlement. Unlike the interim agreements in *Cardizem* and *Terazosin*, which would eventually end with court decisions on infringement, a final settlement sets the entry date by private agreement instead of court determination.

Finally, Schering argues that the agreements are not presumptively anticompetitive because they allowed entry before patent expiration. But it is inconceivable that Schering paid Upsher and for earlier competion rather than later. *See Cardizem*, 105 F. Supp. 2d at 705 (rejecting justification that agreement guaranteed entry, even if generic company eventually lost patent suit).

V. The Payments Had Anticompetitive Effects

A. The Agreements Were Likely to Delay Generic Competition and Injure Consumers

This case does not depend on a finding that the payments are presumptively anticompetitive, because the record shows harm to competition. AHP and Upsher represented potential competition that would have benefitted consumers. Respondents do not deny their expectation that generic entry would take sales and profits from Schering's K-Dur 20, or that Upsher's entry took even more sales than expected. No other product had a similar effect on K-Dur 20 sales. Indisputably, generic K-Dur 20 offered significant benefits to consumers, and delaying its entry would impose high costs on consumers. The agreements provided less competition than would be expected absent the payments, causing tangible anticompetitive harm.

CPF 1217-22. Respondents provide no justification that is sound in theory and based on the evidence. Accordingly, the agreements are unreasonable restraints of trade.

Professor Bresnahan applied undisputed, fundamental economic principles in explaining why these agreements delayed competition. Contrary to Schering's assertions (SAB 61-62), this was not a *per se* analysis. Professor Bresnahan did not assume harm to competition. He determined that the market's economic structure created incentives to delay entry and share revenues, and that the evidence demonstrated that the parties entered into such agreements. CPF 1173-1216.[27] He further explained that, under these circumstances, Schering's payments to AHP and Upsher resulted in negotiated entry dates that provided less competition than the parties expected if the litigation continued, or if the parties settled without a payment. CPF 1217-19.

Respondents' efforts to portray Professor Bresnahan's theory as extreme do not hold up. Courts have had no difficulty understanding that such payments logically will delay competition,[28] and other economists have articulated views similar to Professor Bresnahan's. Indeed, the very article by Professor Gilbert that Schering invokes in its brief (SAB 5, 62) concludes that "[b]ased on the allegations in the public record materials, [the Upsher and AHP

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[27] He also explained that the restraints on the generics' marketing of noninfringing versions of K-Dur are further evidence of the agreements' anticompetitive purpose and effect. Tr. 3:539-40. Contrary to Upsher's assertion (UAB 77), these provisions are not "essential" to settlement. The Commission's recent study of generic drug competition shows that such provisions occurred only in agreements with payments. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* 30-31 (2002) (*Generic Drug Study*).

[28] *See, e.g., Andrx Pharms., Inc. v. Biovail Corp.*, 256 F.3d 799, 809-10, 813 (D.C. Cir. 2001); *Cardizem*, 105 F. Supp. 2d at 706; *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 2d 740, 750 (E.D.N.Y. 2001); *Biovail Corp. Int'l v. Hoechst A.G.*, 49 F. Supp. 2d 750, 766 (D.N.J. 1999); *Eon Labs Mfg., Inc. v. Watson Pharms., Inc.*, 164 F. Supp. 2d 350, 356 (S.D.N.Y. 2001).

settlements] appear to be anticompetitive arrangements to eliminate competition and to divide monopoly . . . profits."[29] Professor Carl Shapiro states that a net payment (in excess of avoided litigation costs) to the challenger "is a clear signal that the settlement is likely to be anticompetitive," because it can be presumed that the patent holder would not make that payment "unless it believed that it was buying later entry than it expects to face through the litigation alternative."[30] Professor Keith Leffler concludes it is anticompetitive for a patent holder to settle a patent dispute by making a lump sum payment to the alleged infringer.[31]

1. Consideration of risk preference does not alter the conclusion of anticompetitive effects

Schering argues that a payment may not delay entry if the patent-holder is risk averse. SAB 63-64. Even a risk averse patent holder, however, can be expected to reach an anticompetitive settlement if it makes a payment. Schering does not contest that for any procompetitive settlement (as defined by the models on which Schering relies), there are a multitude of anticompetitive settlements that the parties prefer. This result holds regardless of the patent holder's risk preference. CPF 1228. Thus, Schering's own models predict that even risk averse parties would choose anticompetitive settlements. CPF 1233-34. Risk aversion,

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[29] Richard J. Gilbert & Willard K. Tom, *Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later*, 69 Antitrust L.J. 43, 76 (2001).

[30] Carl Shapiro, *Antitrust Limits to Patent Settlements* 35-36 (forthcoming in Rand J. of Econ.) (available at http://faculty.haas.berkeley.edu/shapiro/settle.pdf). Although Professor Shapiro acknowledges that such agreements are not necessarily anticompetitive, as there may be justifications, this theoretical possibility does not alter his view that the FTC is right to be skeptical of such payments. *Id.* at 35 and n.29. *See also* Tr. at 6:1251-52 (Bresnahan) (discussing Shapiro white paper on AHP agreement).

[31] Keith Leffler & Christofer Leffler, *Want to Pay a Competitor to Exit the Market? Settle a Patent Infringement Case*, 2 ABA Econ. Committee Newsl. 26 (2002).

therefore, does not undermine the inference that a payment for an entry date provides less competition than is expected in the absence of the payment.

Schering's argument is not limited to instances where uncertainty flows from patent litigation, but would apply equally to any agreement in which the incumbent pays an uncertain entrant not to enter and also guarantees future entry. If the argument had merit, one could never infer that an agreement involving an uncertain entrant harmed competition. Paying AHP to abandon efforts to obtain FDA approval (*see* footnote 5, *supra*), for example, clearly would be anticompetitive. Tr. 34:8085-86 (Bresnahan). But if Schering were risk averse, then by Schering's logic, the agreement could not be deemed anticompetitive, because it might have provided earlier competition than the parties expected (if the AHP waited for the uncertain FDA approval).

In addition to being theoretically and legally unsound, Schering's risk aversion argument is built on a series of nonsequiturs. Schering's citations to the economic literature discuss only individuals' risk preference, not corporations'. Assuming corporate risk aversion is contrary to the standard view in economics that well-diversified corporations like Schering approximate risk neutrality. In modeling corporate behavior, economists generally assume corporations are risk neutral or close to it. Tr. 34:8068 (Bresnahan).[32] Corporations can diversify against most risks by selling a portfolio of unrelated products, and the stockholder can further diversify against risk

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[32] "The standard assumption in most economic models is that the primary objective of a firm is to maximize the firm's profits." Dennis W. Carlton & Jeffrey M. Perloff, *Modern Industrial Organization* 12 (3d ed. 2000); *see also* Tr. 34:8070 (Bresnahan). A firm maximizes its profits by being risk neutral. Tr. 34:8071-72 (Bresnahan). *See also* Oliver Williamson, *Economic Insitution of Capitalism* 389 (1985) (saying that although the assumption is counterfactual, it "may be a close approximation"); Tr. 34:8069 (Bresnahan).

by owning other assets. Tr. 34:8067 (Bresnahan). Corporations structure internal incentives to minimize the effects of their managers' individual risk preferences. Tr. 34:8067 (Bresnahan).[33] Professor Bresnahan's analysis of Schering's actions from a risk neutral perspective, therefore, was sound.[34]

Moreover, in asserting that individual managers could be risk averse, Schering cites writings that are over 20 years old. More recent literature on prospect theory has revealed that individuals' risk preferences vary from decision to decision and depend on how the risks are viewed. When comparing a certain gain and a larger uncertain gain, individuals tend to be risk averse, but when comparing a certain loss and a larger uncertain loss, they tend to be risk *seeking*.[35] If, as Dr. Addanki testified, Schering faced a choice between a certain loss (a settlement with an entry date) and an uncertain but larger loss (in litigation) (Tr. 24:5776-77), then the negotiators, if they deviated from risk neutrality, would in all likelihood have deviated towards risk seeking behavior, not risk aversion.

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[33] Richard A. Posner, *Economic Analysis of Law* 405 (4th ed. 1992) (noting that shareholders ordinarily desire the corporations in which they invest to behave as if risk neutral, and explaining how corporate debt would counteract an individual manager's risk aversion); Frank H. Easterbrook and Daniel R. Fischel, *The Economic Structure of Corporate Law* 53 (1991) (discussing how the purchase of insurance is a mechanism that a risk neutral corporation employs to counteract managers' risk aversion).

[34] Professor Shapiro agrees that risk neutrality is a reasonable assumption in the context of intellectual property dispute settlements. *Antitrust Limits to Patent Settlements* 35, *supra* note 30.

[35] *See, e.g.*, Daniel Kahneman & Amos Tversky, *Prospect Theory: An Analysis of Decision under Risk*, 47 Econometrica 263-91 (1979). Daniel Kahneman recently received the Noble Prize in Economics for this role in identifying and confirming this phenomenon. *See also* Max H. Bazerman *et al.*, *Integrative Bargaining in a Competitive Market*, 35 Org. Behav. & Hum. Decision Processes 294 (1985) (applying prospect theory to context of negotiations).

To maximize its profits, Schering should have been approximately risk neutral, and the evidence confirms that Schering and its managers were acting in a risk neutral manner. The risk at stake in the K-Dur litigation was diversifiable and small relative to Schering's total revenues. CPF 1308. The settlement negotiators were not responsible for K-Dur 20's future revenues. CPF 1309-10. Economic theory and the facts, therefore, support the conclusion that Schering was risk neutral in the patent settlement.

2. State drug substitution laws promote rather than supplant competition

Respondents argue that because of state drug substitution laws, K-Dur 20's loss in sales upon generic entry is due to "government fiat," not the marketplace, and that entry does not benefit consumers. UAB 63; *see also* SAB 73-74. This argument is predicated on incorrect factual assertions, and a failure to understand the purpose of these laws. First, states do not compel patients to purchase generics, as Upsher asserts. UAB 63. If the patient wants the more expensive brand, then the patient can, depending on the law, either veto the substitution or ask the physician to instruct the pharmacist not to dispense a generic. CPF 37-38. Second, Upsher's reliance on state Medicaid laws to argue that states mandate substitution is irrelevant, because under Medicaid the states are acting as purchasers of the drugs, not regulators, and the requirement that pharmacies dispense generics, if cheaper, is merely a condition of state reimbursement.

The history and purpose of the state substitution laws demonstrate their competition-promoting function. Prior to these laws, most states allowed substitution only upon physician authorization, but "[s]ince physicians are an unlikely force behind a switch to lower-cost brands after the patent period has expired, an erosion of the patent-conferred monopoly must depend on

others who have both the power and the incentive to respond to lower prices." Federal Trade Commission, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* 7 (1985). State drug substitution laws corrected this problem. "The laws foster price competition by allowing the only principals who have financial incentives to make price comparisons -- the pharmacist and the patient – to select drug products on the basis of price." Federal Trade Commission, *Drug Product Selection* 7 (1979). Indeed, the Commission and FDA drafted a model state drug substitution law to encourage states to allow substitution among bioequivalent products without a physician's approval. *Id.* at 1-2. This did not supplant competition, but promoted it.

B. The Rule of Reason Does Not Require Proof of When Entry Would Have Occurred Absent the Agreements

Respondents would require proof of anticompetitive effects to a certainty, arguing that we must prove that Upsher or AHP would have won their infringement cases and entered the market earlier than the agreed-upon dates, or that earlier entry was offered during the settlement negotiations, but was moved back in exchange for money. That is not the law. Our burden is to show anticompetitive effects by a preponderance of the evidence, not to establish effects with certainty. *In re Brand Name Prescription Drugs Antitrust Litig.*, 186 F.3d 781, 787 (7th Cir. 1999). As the court of appeals recognized in *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001), proof of the but-for world is always impossible. Respondents' argument that complaint counsel must prove that other factors (such as the patent litigation) would not have prevented earlier entry parallels Microsoft's failed argument that the government must prove that without the foreclosure of Netscape's and Java's distribution channels, those products would have developed into full-blown competition to Windows.

1. The law does not require proof that the generics would have won the patent suits

Schering incorrectly asserts that the settlements' competitive effects "obviously" turn on who would have won the patent cases. SAB 65. An agreement that reduces the likelihood of entry is anticompetitive. For example, an exclusive supply agreement that denied a generic's access to the only active ingredient supplier was ruled anticompetitive and illegal, even though the FDA later banned that material and the generic could not enter the market. *Microbix Biosys., Inc. v. BioWhittaker, Inc.*, 172 F. Supp. 2d 680, 692-95 (D. Md. 2000), *aff'd on other grounds*, 2001 U.S. App. LEXIS 11576 (4th Cir. 2001).

Showing anticompetitive effects does not require proof that the generics did not infringe Schering's patent. Schering's economist, Professor Willig, agreed that a settlement could be anticompetitive without proof that the generic would have won the litigation. Tr. 29:7242-43 (Willig). Recent decisions addressing antitrust challenges to settlement agreements arising in a Hatch-Waxman context have soundly dismissed arguments that patent law or antitrust law requires the plaintiff to establish the likely outcome of the underlying patent case.[36] *In re Tamoxifen Citrate Antitrust Litig.*, 2002 U.S. Dist. LEXIS 16503 (E.D.N.Y. 2002), does not support a contrary result. There, the district court itself acknowledged that its decision was against the weight of authority. *Id.* at *14. Moreover, as the court construed the pleadings, patent invalidity was part of plaintiffs' legal theory. *See id.* at *18-*19. That is not the case here.

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[36] *See, e.g., Ciprofloxacin* 166 F. Supp. 2d at 748-49; *Terazosin*, 164 F. Supp. 2d at 1351-52; *Altman v. Bayer Corp.*, 125 F. Supp. 2d 666, 675 (S.D.N.Y. 2000); *Cardizem*, 105 F. Supp. 2d at 700; *Aetna U.S. Healthcare, Inc. v. Hoechst Aktiengesellschaft*, 54 F. Supp. 2d 1042, 1053-54 (D. Kan. 1999).

City of Pittsburgh v. West Penn Power Co., 147 F.3d 256 (3d Cir. 1998), does not support respondents' "but-for" argument. The court there stressed that it based its holding on a state regulatory scheme that created a fundamentally noncompetitive market, in which entry was permitted only when the existing monopoly provider was "inadequate." *Id.* at 260. A subsequent Third Circuit opinion, *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 401 (3d Cir. 2000), construed the case as having been based on a "regulatory quirk." *Pittsburgh* has no application to this case, which involves a very different regulatory structure.[37]

The *amicus* brief submitted by the Washington Legal Foundation states explicitly what is only implicit in respondents' position -- that a would-be generic entrant and a patent holder can be deemed potential competitors only if the parties knew that the patent was invalid, not infringed, or otherwise not enforceable. WLF 14. This clearly demonstrates the extreme implications of respondents' theory, under which a patent holder could pay any amount of money to a would-be entrant to abandon efforts to enter the market, so long as the patent holder's infringement claim was not a sham. This would be true whether the payment were in consideration of the generic's agreement to forego development of a generic, to withdraw its ANDA before patent litigation was begun, or not to market an approved product.

2. Schering did not show that it would have won the patent suits

Schering fell far short of showing that it was "nearly certain" to win the case against AHP, and its claim that its evidence on this point is "unrefuted" is not supported by the record. SAB 4, 52. Dr. Banakar testified that a proper interpretation of Schering's patent claims, and a

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[37] *See also In re Cardizem CD Antritrust Litig*, 105 F. Supp. 2d 618, 657 (E.D. Mich. 2000) (rejecting claim that *Pittsburgh* precluded antitrust standing for the plaintiffs).

careful comparison of AHP's product to those claims, shows that AHP did not infringe. Tr. 26:6387-92. AHP vigorously defended the infringement litigation, and the record here contains substantial evidence to that effect from the experts AHP intended to call during that trial. CPF 821-40. The presiding judge questioned the merits of Schering's infringement argument,[38] and observed that the case was far from a "slam dunk" for Schering.[39] Schering makes no claim that it would have won the Upsher case. *See* CPF 98-117; *see also* CRB appendix (discussing both cases).

3. Upsher's claim that it could not have entered the market before September 2001 is irrelevant and unfounded

Upsher argues incorrectly that complaint counsel had to prove it would have entered earlier than September 2001 but-for the settlement. UAB 36-37. Even if later events prevented Upsher from marketing its product, that would at most be relevant to damages, not legality. *Microbix,* 172 F. Supp. 2d at 684-95. Upsher offers no basis for concluding that, had it won, it would not have marketed its product until September 1, 2001. Schering agrees that Upsher's victory in the patent litigation would have accelerated its entry. SAB 1.

Dr. Kerr's predictions shed no light on the likely course of the Schering/Upsher litigation, because he relied on a data set that consisted only of damages cases, which Hatch-Waxman cases do not involve. *See* CPF 1383-86, 1387-93, 1394-96. His estimates are contrary to the findings of the Commission's study on generic drug competition. *Compare* Tr. 26:6261-70 (Kerr assumes

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[38] Tr. 15:3387-89 (Miller) (agreeing that judge was concerned that Schering's patent would be invalid if it were read as broadly as Schering proposed). *See also* Tr. 14:3038-39 (Banker).

[39] Tr. 14:3038-39 (Banker); 15:3387-89 (Miller).

36% probability of reversal and remand) *with Generic Drug Study* at 21 (reversal rate in Hatch-Waxman litigation involving Paragraph IV certifications was 8%). Similarly, Professor Adelman's testimony, which Upsher and the WLF take completely out of context, provides no basis for concluding that the litigation would have persisted for five years, because he testified that in his experience most cases went much faster. Tr. 32:7772-73. The Commission's *Generic Drug Study* reported that cases it considered took an average of 25 months and 13 days from complaint to district court decision, and an additional 12 months and 7 days if there was an appeal. *Id.* at 47. The Schering/Upsher case was about to go to trial approximately 18 months after it was filed. CX 225; Tr. at 15:3549 (Hoffman). Upsher anticipated entry no later than January 1998, even with an appeal. CX 256.

The record does not support Upsher's suggestion that, absent the certainty of the entry date, it would not have been in a position to launch its product before September 2001. UAB 38-41. Before the June 1997 settlement agreement, Upsher was planning to launch its product well before 2001. [redacted][40] Upsher then took steps to launch its generic by early 1998. CPF 125-28 (Upsher projected entry by January 1998); CPF 130-31 (undertook marketing preparations and projected launch quantities); CPF 132, 136-39 (scheduled validation batches and reserved time for launch production). Its later decision to

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[40] [redacted]

invest in additional plant and equipment was due to growth in the K-Dur 20 market between 1997 and 2001, necessitating a larger number of tablets for launch. CPF 157, 160-61

4. The 180-day exclusivity period and AHP's decision to exit the market have no impact on the legality of the Schering/AHP settlement

Schering argues that the AHP agreement had no competitive effect because Upsher's 180-day exclusivity would have blocked AHP's final approval until April 2002, and AHP exited the oral generic market before then. SAB 70.[41] These facts are irrelevant to the agreement's legality, which must be judged at the time it was entered, January 1998. At that time, the agreement removed the possibility that AHP could enter prior to January 2004. There was considerable uncertainty about whether Upsher forfeited its exclusivity period by settling with Schering, and there was a significant possibility that AHP would not be blocked, or that a litigated decision in AHP's favor would trigger Upsher's exclusivity well before September 2001. CPF 911-22. AHP's exit clearly was unforeseeable at the time of the agreement (or Schering would not have needed to pay to settle the case).

The *Competitor Collaboration Guidelines* are not to the contrary. SAB 70. They merely state that enforcement agencies will assess the effects of a competitor collaboration at the time of possible harm to competition, "whether at formation of the collaboration or at a later time, as appropriate." FTC & DOJ, *Antitrust Guidelines for Collaborations Among Competitors* § 2.4 (2000). Thus, a collaboration that does not endanger competition at its formation may nevertheless be subject to enforcement action if harm to competition develops later. This hardly

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[41] Schering's interpretation of the Commission's complaint is wrong. *See* Response to AHP's Motion to Compel Complaint Counsel to Confine Their Theories to the Allegations in the Complaint (Aug. 17, 2001).

demonstrates that an agreement that threatened anticompetitive effects at the time it was made escapes liability because subsequent events mitigated or eliminated its effects.

5. Lack of alternative settlements

Nor are we required to show that an earlier entry date was offered during the settlement negotiations, and rejected in favor of payment of money.[42] *See* ID 103, UAB 47 n.9, SAB 61. Both Upsher and AHP asked for earlier entry. Since Schering refused to consider an earlier date, the negotiations necessarily turned to the split of monopoly profits. That the parties agreed first to the entry date, and then to the amount of the payment, does not suggest that the payment was not for the entry date. On the contrary, it confirms the link between the money and the date, since the "agreement" on the date was not an agreement at all until the amount of the payment was settled.

C. Determining the Likely Competitive Effects of Payment for an Entry Date Does Not Depend on Assessing the Merits of the Underlying Patent Cases

Schering argues that proof of anticompetitive effects requires a direct retrospective inquiry into the merits of the patent litigations. Such an inquiry is unnecessary, and would not be helpful, because it cannot be done in any meaningful way.[43]

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[42] It is unreasonable to assume that such evidence ever would be available. It is much too easy for the parties to avoid making explicit what is implicit in their behavior. *See United States v. W.F. Brinkley & Son Constr. Co.*, 783 F.2d 1157, 1160 (4th Cir. 1986) (accepting claim that bid-rigging agreement did not influence defendant's bid would lead to self-serving testimony in virtually every case).

[43] It is incorrect that we maintain that the inquiry should not be undertaken simply because it is too difficult, as Schering asserts. SAB 65.

1. Assessment of the parties' actions is the best indicator of competitive effects

The parties to the infringement suits are in the best position to assess the strength of their respective cases. They have the most complete information and can best judge what will further their competitive interests. Accordingly, the parties' conduct in settlement provides the best indicator of how they view the litigation's likely outcome. It is appropriate to conclude, therefore, that a settlement with payment delays entry relative to the parties' expectation of the litigation's likely result. *See* Tr. 4:610, 614 (Bresnahan). Schering's post-hoc investigation of the patent merits will not present a more accurate portrayal of the likely outcome of the case. *See* CPF 1345-63.

2. Assessment of the patent merits would not be reliable

The undertaking Schering urges cannot provide any reliable information that would assist in assessing the agreements' likely competitive effects. There is no "objectively" determinable likely outcome of settled patent litigation. The outcome of litigation depends on many factors that cannot be predicted, and opinions on the likely outcome of cases that settle can never be tested. CPF 1345-50. Schering's expert, Mr. O'Shaughnessy, a patent trial lawyer, testified that patent litigation is unpredictable. Tr. 29:7065. There is no recognized methodology for handicapping trials or for testing the reliability of predictions of litigation outcomes. *See* Tr. 15:3296 (Miller); Tr. 34:8095-96 (Bresnahan). Moreover, a fundamental condition of the original lawsuits – the adversarial relationship between the patent holder and the alleged infringer – has changed. In this proceeding, the alleged infringer has no incentive to defend its product against the infringement claim, and has made no effort to do so. What Schering is asking for, in reality, is an after-the-fact decision as to what the outcome *should have been*.

Respondents would determine the probabilities based on far more limited information than the parties had available to them at the time of the settlement. Any attempt to evaluate the merits of the cases in hindsight would exclude the parties' own contemporaneous assessments, which the respondents have withheld as privileged.

Schering's approach requires a high level of precision, because a small error in assessing the litigation probabilities, and thus in the expected entry date under litigation, could cause large errors in assessing the competitive effect of the agreement. Tr. 34:8085 (Bresnahan). Each day of delayed generic entry harms consumers. One of Schering's forecasts, for example, estimates that generic competition would save consumers over $4 million in a single month. CX 133; Tr. 6:1241 (Bresnahan). Schering has not contended that such precision is possible. Tr. 13:2775 (Nields) ("[W]e don't purport to try to be mathematical about it."); Tr. 29:7117-19 (O'Shaughnessy) (any prediction of the outcome is only be a "rough approximation"). That means that even if it were possible to assess the probability of entry to within a 10% range, anticompetitive agreements that cost consumers tens of millions of dollars would go unidentified.

The subjective opinion of Schering's patent law expert about the relationship between AHP's entry date and the merits of the patent litigation is entitled to no weight. The testimony reflects only his personal view of the merits of the patent case, based on a limited review of the record of that proceeding. He admitted that the likely outcome of patent litigation cannot be predicted with certainty, and that it is impossible to quantify accurately the odds of a party prevailing at trial. His opinion provides no insight into the parties' views of the likely outcome of the litigation. As a patent lawyer with no expertise in antitrust law or economics, Mr. Miller is not qualified to render an opinion on the reasonableness or competitive effects of the 2004 entry

date. And he was not aware of, and did not consider, Schering's payment to AHP. *See* CPF 1351-63,1374-77.

3. Assessment of the probabilities the patent holder would win is insufficient

Predicting the probabilities of success in the infringement litigation reveals nothing about the settlement's competitive impact. While Schering argues that our approach requires too much complexity (SAB 66), Schering's approach is impossible. Its own expert stated that assessment of the actual competitive effects of the agreement would require analysis of myriad factors, including the possibility of entry by another generic, the incumbent's profits before entry, the entrant's and incumbent's profits after entry, and the deadweight loss under both the monopoly and duopoly conditions. As Professor Willig admitted, these calculations are very difficult. CPF 1370. He also agreed that one would have to know the likelihood of entry by a superior brand product, whether some other factor would cut demand, and how the market size would change over time. Tr. 34:7256-60. In fact, Professor Willig refused to endorse any test, while conceding that settlements could be anticompetitive. Tr. 34:7255, 7283. Neither of respondents' economists attempted to analyze the agreements under Schering's standard. Tr. 25:5940-42 (Addanki); Tr. 29:7250-60 (Willig). In advocating a test for competitive harm that cannot be done reliably, respondents urge a rule that would immunize all settlements involving payments not to compete.

VI. Respondents Offer No Plausible Procompetitive Justifications

The justifications respondents offer for the payments are implausible, not cognizable, or do not relate to the payments. They provide no reason to disregard the obvious inference and proof of anticompetitive effects.

A. Schering's Models Do Not Provide a Plausible Justification

A legitimate justification must, as a matter of theory, predict a procompetitive result and be based in fact. Schering's models (many of which are based on risk aversion) satisfy neither requirement. The models have three theoretical failings. First, the models do not explain why parties would ignore their incentive to maximize profits and fail to choose an anticompetitive settlement – a point that Schering does not and cannot contest.[44] Second, as discussed earlier, the justifications apply whenever there is uncertain competition (not just to patent litigation); thus, their acceptance would prevent antitrust law from protecting uncertain competition. Finally, the models require that the patent-holder have a monopoly. If these models justify payments, then patent holders with monopoly power would have an advantage over other litigants in settling litigation.

B. Generic Entry Prior to Patent Expiration Does Not Justify the Agreements

Respondents' contention that the agreements are procompetitive because they permitted entry prior to patent expiration is not cognizable. Anticompetitive agreements that distort the competitive dynamic between the parties cannot be justified on the ground that consumers are better off with certain, but less than expected, competition. *See, e.g., Catalano v. Target Sales,*

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[44] Indeed, a striking feature of many of Schering's models is that one or both parties would think they were entering into an anticompetitive agreement, but then would fail to implement an agreement that effectuated that intent. CPF 1254-55.

Inc., 446 U.S. 643, 647 (1980) ("It is no excuse that the prices fixed are themselves reasonable.").

C. The Benefits of Settlement Do Not Justify the Payments

Respondents' argument that the benefits of settlement justify these agreements is meritless. Respondents have not demonstrated that payments to stay off the market are reasonably necessary to achieve a settlement. In general, one-way payments to the purported infringer are not necessary to settle litigation. CPF 1413-25. The record contains no evidence that a payment from a patent holder to an alleged infringer was needed to reach a procompetitive settlement in any patent case. If payment was necessary here, it is because Schering needed it to get the agreed-to entry date. Schering's claim (SAB 64) that it paid the minimum necessary to get the AHP settlement, after the date was agreed to, confirms rather than refutes this fact. It shows that $15 million was the amount that Schering had to pay for the 2004 entry date. Moreover, the cost to consumers of delayed entry dwarfs the resource savings from settlement. CPRF 864-69.

Schering's assertion that the $60 million payment to Upsher somehow created value that facilitated settlement of the patent dispute (SAB 11 n.5) is inconsistent with its claim that the Niacor-SR license was worth that money. The transaction would create value in only two ways: by extending the expected period of monopoly, or by transferring Niacor-SR to a licensee that uniquely values the asset. There is no evidence of the latter, and a great deal of evidence of the former.

There is no support for the contention of the *amici* that finding these agreements illegal will chill patent settlements and discourage generic companies from making Paragraph IV

certifications. The rule of law we seek would not prohibit settlements, but only reverse payments in the context found here. There is no basis for their assertion that this case will raise barriers to generics' exit from patent litigation (GPA 10), or that generics will be "unable to settle costly and time-consuming patent litigation." WLF 20. And the actual experience, as reported by the Commission's *Generic Drug Study*, is that while publicity has put an end to settlements with payments, settlements of Paragraph IV cases have continued. *Id.* at vii-viii, 27. Even "side deals" are rare in settlements between brand companies and generics. *Id.* at 31 (only two agreements included licenses for drugs other than the one subject to litigation).

D. Upsher's Other Purported Procompetitive Benefits Do Not Justify the Payments

Most of Upsher's various other proffered procompetitive benefits suffer from a common flaw: they are not reasonably related to the payment. The claimed benefits flow from settlement of the litigation (resource savings from settlement) or the granting of licenses (obtaining overseas distribution of Upsher products), neither of which is challenged, or they result simply from Upsher's receipt of the $60 million payment (a return on Upsher's R&D investment). Others are competitively insignificant (avoiding patent litigation over Klor Con M10[45] and entry of Qualitest and Warrick).[46] None justifies payments to stay off the market.

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[45] The patent issues concerning Klor Con M10 and Klor Con M20 were identical, since Upsher used the same coating material for both. CPF 1406. Upsher never explains why an agreement resolving the infringement claim as to Klor Con M20 would not have resolved the issue for M10 as well.

[46] Since Upsher manufactures Qualitest's product and Warrick is a Schering subsidiary, these companies added no new competitors to the market.

E. The Magistrate's Involvement in the AHP Negotiations Does Not Mean That the Agreement was "Fair" to Consumers

Schering's reliance on the magistrate's involvement in settlement negotiations (SAB 70) is unavailing. First, Schering's lengthy statement of supposedly "undisputed" facts (SAB 51) regarding the role of the trial judge and magistrate judge in those negotiations (SAB 46-51) is neither undisputed nor supported by record evidence. We have previously taken issue with Schering's misstatement of the nature and extent of judicial involvement in the settlement agreement. *See* CPTB 42-44, 78-81; CPRF-S 2.17, 2.28, 2.84, 2.86; CAB 70. While no longer expressly advancing earlier claims that the judge or the magistrate coerced the settlement and "approved" its terms, Schering continues to present a description of the negotiations that presents as "fact" matters whose only support is hearsay testimony that was not admitted for the truth of the matters asserted.[47]

In any event, the magistrate's involvement provides no indication that the settlement terms were reasonable or "fair" to consumers. The magistrate's role was to facilitate a settlement, not to conduct an antitrust review (indeed, he had no authority to disapprove a settlement agreed to by the parties).[48]

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[47] Schering witnesses repeatedly testified as to what the trial judge and magistrate allegedly said, but this hearsay testimony was not admitted for the truth. *See* Tr. 11:2487, 11:2500, 11:2506, 11:2511, 11:2517, 11:2530, 11:2533, 11:2537, 11:2577, 12:2608, 12:2704, 12:2708 (Nields); Tr. 12:2608 (Chappell).

[48] Schering's off-hand suggestion (SAB 46 n.17) that the agreement "may" be subject to *Noerr Pennington* protection does not merit a response.

VII. The Agreements Are Also *Per Se* Unlawful

None of the reasons against *per se* treatment advanced by respondents or the *amici* is persuasive. The fact that the agreements arose from settlement of patent litigation plainly does not make *per se* condemnation inappropriate. *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963); *Masonite*, 316 U.S. 265. *Standard Oil Co. v. United States*, 283 U.S. 163 (1931), is not to the contrary. It merely demonstrates that antitrust law does not necessarily condemn agreements to cross-license potentially blocking patents and to share the resulting royalties, because those types of agreements could provide efficiencies. *Id.* at 171. This case, however, does not involve owners combining their intellectual property to produce a product that otherwise would not exist, or an agreement facilitating immediate new entry by the alleged infringer in exchange for compensation to the patent holder.

Respondents' assertion that this case involves "novel" practices also fails. The critical factor in assessing whether the *per se* rule applies is the economic substance of the challenged conduct, not the industry in which it arises. In appropriate cases, the Supreme Court has not hesitated to find a practice *per se* illegal, even when the restraint is not identical to ones condemned in the past, or occurs in a context that has never before been considered by an antitrust court.[49]

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[49] *See, e.g., Catalano*, 446 U.S. at 648-50; *Arizona v. Maricopa County Med. Ass'n*, 457 U.S. 332, 349-51 (1982).

VIII. Schering Had Market Power and a Monopoly at the Time of Its Agreements With Upsher and AHP

Respondents spend a significant portion of their briefs arguing that Schering lacked monopoly power, ignoring that allegations of Sherman Act Section 1 violations only require proof of market power. Under Section 1, proof of competitive effects proves market power. *See FTC v. IFD*, 476 U.S. 447, 460-61 (1986). Moreover, the ALJ, by ruling that "Complaint Counsel cannot prove an effect without first proving by market definition what is claimed to be affected" (ID at 85-86), like the respondent in *Toys "R" Us, Inc. v. FTC*, "has things backward."

> [Toys "R" Us] seems to think that anticompetitive effects in a market cannot be shown unless . . . the Commission, first proves that it has a large market share. This, however, has things backwards. As we have explained elsewhere, the share a firm has in a properly defined relevant market is only a way of estimating market power, which is the ultimate consideration. The Supreme Court has made it clear that there are two ways of proving market power. One is through direct evidence of anticompetitive effects.

221 F.3d 928, 937 (7th Cir. 2000) (citations omitted).

Because blocking generic K-Dur 20's entry prevented a massive loss of sales by Schering and a substantial price reduction for consumers, the anticompetitive effects of the agreements are demonstrated directly, thus obviating the need to define a market for Section 1 purposes.[50]

With respect to Sherman Act Section 2, the ALJ and respondents rely on the faulty premise that a monopoly can only be proven by defining a relevant antitrust market using the

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[50] Although respondents argue that Professor Bresnahan's model requires that Schering have a monopoly in its legal sense, Professor Bresnahan adopted the convention, common among economists, of using the terms monopoly and market power interchangeably. *See generally* Carlton & Perloff, *supra* n.32 at 92 ("[t]he terms *monopoly power* and *market power* typically are used interchangeably to mean the ability to profitably set price above competitive levels"). In Professor Bresnahan's opinion, any agreement that delayed entry of a lower-priced generic that would have taken substantial sales from K-Dur 20 would be anticompetitive. Tr. 3:464.

factors set forth in *Brown Shoe Co. v. United States*, 370 U.S. 294 (1962). *Brown Shoe*, however, is neither the only nor necessarily the preferred method of defining markets. For example, the *Merger Guidelines* are a vehicle for how to think about those and other factors more rigorously. The point is, we use the evidence available to determine the smallest group of products and firms necessary to monopolize a market.

In this case, there is abundant evidence that generic K-Dur 20 was expected to (and does) provide significant competition to branded K-Dur 20 that is qualitatively different from the insignificant competition provided by other potassium supplements. This evidence establishes that the relevant market is K-Dur 20 and its generics. Further, because there was no entry into this market until September 2001 and Schering's market share was 100%, Schering had a monopoly in that market.

A. There Is Abundant, Undisputed Evidence That K-Dur 20 and Its Generics Are a Relevant Market

As set forth in detail in our appeal brief, the evidence – largely undisputed by respondents (and essentially ignored by the ALJ) – shows:

1. In the years prior to generic K-Dur 20's entry, K-Dur 20's sales continued to grow compared to sales of lower-priced potassium supplements, despite yearly price increases relative to generic 8 and 10 mEq products (CPF 63-64, 972-87);

2. In the years prior to generic K-Dur 20's entry, the entry of other generic potassium supplements had little or no effect on K-Dur 20's sales, profits, or prices, but did affect the sale of other branded potassium supplements (CPF 952, 972-87, 994, 1001-02, 1026, 1034; CAB Figures 1, 6-7[51]);

3. Schering, Upsher, and ••••• each forecast that generic K-Dur 20's entry would quickly take a large share of branded K-Dur 20's sales and would significantly

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[51] The sources for Figure 7 were inadvertently left off of our initial Appeal Brief. Figure 7 is based on CX 62-65 and 81-82.

lower the average market price paid for K-Dur 20 and its generics (CPF 83-84, 96-97, ••••••••••••••, 955-57, 962, 964-67, ••••••••••••••);

4. Schering recognized that it could profitably sell its own generic K-Dur 20 at prices 50% lower than its identical brand (CPF 955, 1115);

5. When it finally entered the market in September 2001, Upsher's generic K-Dur 20 was sold for half the price of branded K-Dur 20 and immediately took a very large percentage of K-Dur 20's sales (CPF 988-92).

Taken together, this evidence establishes that K-Dur 20 and its generic equivalents are a relevant market and that Schering had monopoly power – "the power to control prices" – in that market. *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956).

Respondents' primary attack on this evidence is to argue that K-Dur 20 must not be a monopoly because: (1) generic K-Dur 10's entry had the same effect on branded K-Dur 10 as generic K-Dur 20's entry had on branded K-Dur 20, and (2) Professor Bresnahan allegedly conceded that K-Dur 10 was not a monopoly. This argument is based on a distortion of Professor Bresnahan's testimony that appears in Upsher's post-trial brief (UPTB 90) and that the ALJ adopted. IDF 102.

Professor Bresnahan was never asked to study whether K-Dur 10 was a monopoly, nor did he provide testimony on the issue. The very testimony cited by Upsher shows that Professor Bresnahan provided no such opinion:

Q. And the only monopoly you see on this page, SPX 2069, in your view is K-Dur 20, sir?
A: I don't think that's accurate. It's the only one I've looked at.
Q: Alright. Now, these other products, like K-Dur 10, you haven't looked at whether or not K-Dur 10 is a monopoly in your own view?
A: I have not.

Tr. 34:8147 (Bresnahan).

Although respondents assert that K-Dur 10 was not a monopoly, neither they nor their experts provide any support for this. Nevertheless, the issue in this case is not K-Dur 10, but K-Dur 20 and its generics. In the absence of generic K-Dur 20, Schering increased K-Dur 20's prices without losing sales, and when a cheaper generic K-Dur 20 entered, Schering lost most of its K-Dur 20 sales.

B. Relying on Other Methods to Define the Market Is Unnecessary

Upsher provides a laundry list of other methodologies – including price tests, econometric studies, and the measurement of price elasticity – that complaint counsel's economic expert, Professor Bresnahan, might have performed. UAB 57-58. The ALJ cites these in his Initial Decision. IDF 419-29; ID 91, 93-94. Because Professor Bresnahan did not perform these tests, respondents now ask the Commission to find that complaint counsel did not prove monopoly power. UAB 47-49, 57-58, 73.

Professor Bresnahan knows these methodologies well. He is one of the pioneers in developing methodologies for measuring market power.[52] As he testified at trial, the direct evidence of anticompetitive effects is so strong that it was not necessary to use other methodologies to define the market. Tr. 6:1222-25 (Bresnahan). Neither Upsher nor the ALJ ever provides any basis for concluding that these tests were necessary in this case, nor do they cite to any evidence that, had these tests been performed, they would have demonstrated Schering lacked monopoly power.

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[52] *See, e.g.*, Timothy F. Bresnahan, *Empirical Studies of Industries with Market Power*, 2 Handbook of Industrial Organization 1011 (R. Schmalensee & R. D. Willig, eds.) (1989); Jonathan B. Baker & Timothy F. Bresnahan, *Empirical Methods of Identifying and Measuring Market Power*, 61 Antitrust L.J. 3 (1992).

Upsher's laundry list notwithstanding, it can point to no evidence undermining Professor's Bresnahan's conclusions that: (1) K-Dur 20 was more expensive than the generic 8 and 10 mEq potassium supplements; (2) K-Dur 20 did not lose sales to those generics despite that price difference increasing over time; and (3) generic K-Dur 20 entry was expected to and did take substantial sales from K-Dur 20. Further, although Upsher argues that determining potassium supplement prices requires complicated statistical analysis, no such analysis was needed to show that generic 8 and 10 mEq products were significantly less expensive than K-Dur 20. Upsher's documents and witnesses, and Schering's documents and expert, Dr. Addanki, confirm that, at the time of the Schering/Upsher agreement, K-Dur 20 was priced substantially higher than generic 8 and 10 mEq products (CPF 1075 and USX 401 at Upsher-Smith-FTC 163369; CPF 972; CPF 1101; CX 20 at SP004040), and that K-Dur 20's price rose relative to the generics' prices. CPF 974; CPF 973; CX 30 at Upsher-Smith-FTC 152956 ("K-Dur 20 . . . continues to command a high price in the absence of generic competition."); USX 392 at Upsher-Smith-FTC 151426 ("K-Dur 20 continues to gain share and implement price increases").

Upsher goes on to argue that Professor Bresnahan did not analyze K-Dur 20's rebates or costs. UAB 57-58. First, because rebates on K-Dur, as a percentage of net sales, were essentially constant or decreasing between 1995 and 2000, respondents' suggestion that Schering was lowering K-Dur 20's price through rebates is baseless. CX 695. Second, record evidence confirms that Schering's net price for K-Dur 20 increased, given that K-Dur 20's net sales increased at a faster rate than the total quantity of its prescriptions between 1996 and 1998 (CX 1389 at SP2300016-17) and between 1998 and 2000. CX 64-65, 695. Finally, because

Schering's product margin on K-Dur, as a percentage of net sales, increased during the same time period (CX 695). K-Dur 20's price increases were not cost-driven.

C. The ALJ and Respondents Misconstrue "Reasonable" Interchangeability

The heart of the ALJ's and respondents' product market discussion is the argument that many potassium supplements are "functionally interchangeable" with or "therapeutically equivalent" to K-Dur 20. ID 87-89; UAB 49-50, 53-54, 67. It is undisputed that there are many pharmaceutical products that contain potassium chloride and that can be used to treat potassium deficiency. But this is little, if any, proof that those other therapeutic agents are "reasonable" substitutes for K-Dur 20 in the antitrust sense. For as the Supreme Court teaches in *du Pont*, reasonable interchangeability is not only a question of the functional substitutability among products, but must take into account "price, use, and qualities." 351 U.S. at 404.

K-Dur 20 has a number of important characteristics that distinguish it from the other potassium supplements. CPF 1037-70. This helps explain why it could be priced significantly higher than most other potassium supplements and take annual price increases relative to the other products, and nonetheless continue to increase its sales. CPF 63-64, 972-87.

Moreover, when legal restrictions prevent effective price competition between two products, the products are not reasonably interchangeable and belong in different antitrust markets. *See United States v. ADM Corp.*, 866 F.2d 242, 246 (8th Cir. 1988) (finding because government price supports raised price of sugar, sugar is not in same market as high fructose corn syrup). Here, the requirement that a physician must approve switching a prescription from K-Dur 20 to a non-AB rated potassium supplement prevents significant switching (CPF 1011-

13); consequently, non-AB rated potassium products are not reasonably interchangeable with K-Dur 20.[53]

Upsher and the ALJ also cite *Warner Lambert Co.*, 87 F.T.C. 812 (1976), for the proposition that pharmaceutical products belong in the same market if they are therapeutically equivalent and business documents discuss a single market, even when there is low cross-elasticity of demand between products. ID at 89-90; UAB 60. In *Warner Lambert*, however, the Commission defined the market to include various thyroid products, despite the low cross-elasticity of demand, because it found that the products could constrain "a substantial [price] increase." 87 F.T.C. at 877. The case says nothing about how a court should analyze a market where one form of competition (e.g., a generic) provides a unique constraint on the other (e.g., the brand). Moreover, both the ALJ and Upsher ignore the implications of *Warner*, which measures market shares by revenue, not units. *Id.* at 877-78. Under that methodology, Schering's market share of an all potassium supplements market would have grown from 58% in 1997 to 67% in 2000, which is more than sufficient to support a finding of monopoly power. CPF 1073.

D. Respondents Make a Number of Basic Economic Mistakes

Respondents make a number of basic economic mistakes. First, respondents argue that a number of other potassium supplements were priced similarly to, or even above, the price of K-Dur 20. UAB 49, 55-56. This proves nothing. To draw any meaningful conclusion from such

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[53] Upsher's argument that switching at the pharmacy level is easy because 60% of potassium prescriptions are written as "KCl . . . and pharmacists decide how to fill [them]" (UAB 65), misrepresents the testimony of Upsher's witness, who actually testified that, in 1996, 60% of prescriptions were written for KCl or K-Dur 20. Tr. 20:4750-51 (Dritsas). At that time, any substitution for K-Dur 20 would require physician authorization.

evidence one must also look at whether these products were quantitatively important in terms of the number of units sold – which they were not. CPF 1108.

Second, respondents turn around and argue that record evidence shows that the 30% price difference between K-Dur 20 and non-AB rated generics caused some switching from K-Dur 20 to generics. UAB 55. This argument exhibits another basic economic fallacy (the "cellophane" fallacy): the notion that a firm with monopoly power can charge any price it wants. But as Judge Learned Hand recognized long ago, "substitutes are available for almost all commodities, and to raise the price enough is to evoke them."[54]

Third, respondents argue that Schering's large marketing and advertising expenditures show that there was a lot of competition. UAB 67. The fact that Schering advertised K-Dur 20 tells us nothing about Schering's monopoly power, for even a monopolist wants to increase the demand for its product in order to increase its sales (at the monopoly price). Tr. 6:1229-30 (Bresnahan). *See also* CPF 1124.

Lastly, respondents argue that Schering gave millions in rebates to its K-Dur 20 customers, implying that this would not have been done by a monopolist insulated from competition. UAB 62-63. Here too respondents have it wrong. Absent evidence that Schering's rebates reflect differences in the costs of serving different classes of customers, selective rebating actually implies that Schering had market power, because it can price discriminate among its customers. *See, e.g., In re Brand Name Prescription Drugs Antitrust Litig.*, 186 F.3d 781, 783 (7th Cir. 1999) (Posner, J.) ("[p]rice discrimination implies market power"); CPF 1092.

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[54] *United States v. ALCOA*, 148 F.2d 416, 426 (2d Cir. 1945) (citations omitted). *See also* Richard A. Posner, *Antitrust Law: An Economic Perspective* 128 (1976) ("at a high enough price even poor substitutes look good to the consumer").

E. That a Patient Can Take Two 10 mEq Potassium Supplements for One K-Dur 20 Proves Nothing

Respondents make much of the possibility of taking two 10 mEq potassium supplements instead of one K-Dur 20. UAB 49-50; SAB 72. Prior to the launch of its generic 20 mEq product, Upsher had a program that sought to promote this practice among physicians. Except for a period when there was a shortage of K-Dur 20, this program was unsuccessful. CPF 1024-26. Rather than proving that 10 mEq products compete with K-Dur 20 in any economically meaningful way, Upsher's failed substitution program demonstrates that 10 mEq products did not constrain the pricing or sales of K-Dur 20.

F. A Single Brand or Product Can Constitute a Relevant Product Market

Contrary to respondents' insinuations, a single brand or product can constitute a relevant product market. Indeed, the Supreme Court expressly found that "in some instances one brand of a product can constitute a separate market." *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 482 (1992) (citations omitted). As Judge Posner observed in *Brand Name Prescription Drugs*, "[i]t would not be surprising . . . if *every* manufacturer of brand name prescription drugs had some market power." 186 F.3d at 787. To reach such a conclusion, as the Supreme Court teaches in *Kodak*, one needs to look at the "commercial realities." 504 U.S. at 482 (citations omitted).

The commercial realities show that only generic K-Dur 20 had the potential to take significant amounts of business away from Schering's K-Dur 20. Prior to generic entry, K-Dur 20 had features that no other potassium supplement possessed, including ease of dosing and microencapsulation. CPF 1037-70. These differences were sufficiently significant that Schering's counsel, Mr. Nields, during his opening heralded Schering as "the only one who

figured out [how] to make a 20 [mEq] dosage." Tr. 1:51. Schering now not only argues that all potassium supplements are part of a "crowded market" (SAB 71), but its counsel is reduced to disparaging K-Dur 20 as nothing more than a "horse tablet." SAB 72. The commercial realities, however, show that no other potassium supplement could have the impact on K-Dur 20's sales and profitability that entry of a generic K-Dur 20 was expected to have and did have.

G. Schering's Agreements With Upsher Excluded Competition

Both Schering and Upsher have proclaimed that their agreement got a low-priced generic to market sooner than might have occurred by continuing the patent infringement litigation. Schering's counsel, Mr. Nields, for example, asserted in his opening statement at trial that consumers are enjoying "low prices" for generic K-Dur 20 today "because of the settlement." Tr. 1:38-39. Similarly, Upsher's counsel, Mr. Curran, during his opening claimed that Upsher is "the consumer's best friend," and that "[i]ntroducing lower-priced generic products is Upsher-Smith's mission, it's its life blood, it's what they do, and it's what they did here . . . ." Tr. 1:74-75. If generic entry is good for consumers and is procompetitive (which it is), then the reciprocal must be true as well: delaying generic entry by agreement among competitors harms consumers and is anticompetitive.[55]

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[55] *Cf.* Richard Schmalensee, *Another Look at Market Power*, 95 Harv. L. Rev. 1789, 1806 (1982) ("Evidence that competitors have conspired to . . . divide markets is treated as very good evidence that those competitors have market power.") (citations omitted); Robert H. Bork, *The Antitrust Paradox*, 269 (1978) ("Very few firms that lack power to affect market prices will be sufficiently foolish to enter into conspiracies to fix prices. Thus, the fact of agreement defines the market.").

II. The ALJ's Finding of an "All Oral Potassium Supplement" Market Defies Commercial Realities

To accept the ALJ's finding that the relevant market consists of "all oral potassium supplements" (IDF 29), one would have to conclude that the entry of generic K-Dur 20 into this "crowded market" (SAB 71) made little difference to consumers and to competition.

Record evidence of the commercial realities belies the ALJ's findings. There is no doubt that patients who take generic K-Dur 20 and those who pay the bills for prescription drugs realized significant savings when generic K-Dur 20 finally became available in September 2001. There is no doubt that Schering, Upsher, and AHP were aware of the effect that generic entry would have on K-Dur 20's sales when they entered their illegal agreements. And there is no doubt that their illegal agreements, by delaying the entry of generic K-Dur 20, harmed competition and consumers.

Accordingly, the relevant market in which to analyze the anticompetitive effects of Schering's agreements with Upsher and AHP is K-Dur 20 and its generic equivalents. This market accurately reflects the unique competitive dynamic that typically exists between a branded drug and its generic counterpart. Indeed, it is precisely this unique competition – the fact that generic entry effectively commoditizes its branded equivalent overnight – that explains why Schering was willing to pay Upsher and AHP to delay generic entry.

IX. Upsher's Defense of the ALJ's Improper Procedural Rulings Is Unavailing

A. Upsher May Not Use a Confidentiality Agreement With IPC to Interfere With Law Enforcement

Upsher asserts that it was "well within its rights" invoking a confidentiality agreement to induce IPC to terminate its cooperation with complaint counsel. But all the cases Upsher offers

in support involve private litigants, and raise no concern about impeding public law enforcement. *EEOC v. Astra USA, Inc.*, however, recognizes the overriding public interest in encouraging communications with a law enforcement agency. 94 F.3d 738 (1st Cir. 1996). In enjoining enforcement of settlement agreements that barred voluntary communications with the EEOC, the court expressly distinguished between the public interest in EEOC enforcement of the civil rights laws and a private party's interest in pursuing litigation for recompense. *Id.* at 744 n.5. And *Astra* squarely rejected the suggestion that law enforcement agencies must resort to formal discovery in order to trump a private confidentiality agreement. *Id.* at 745.

Upsher's suggestion that the principles *Astra* articulates are limited to the investigatory phase of law enforcement has no basis in law or logic. As the *Astra* court noted, "any agreement that materially interferes with communication between an employee and the Commission sows the seeds of harm to the public interest." *Id.* at 744.

Absent an interest in enforcement of a confidentiality agreement with IPC that outweighed the substantial public interest in FTC law enforcement, the agreement was unenforceable. *See, e.g., Town of Newton v. Rumery*, 480 U.S. 386, 392 (1987) (promise unenforceable if interest in its enforcement is outweighed by public policy). Upsher offers no plausible argument that informal conversations between IPC employees and FTC staff would impair its interest in keeping sensitive business information confidential. Disclosures by IPC to complaint counsel would not place such information in the public realm (in contrast to the threatened disclosures to private parties in cases cited by Upsher), and ample measures were available to guard against improper disclosures at trial.

B. Professor Bresnahan's Knowledge of Industry Reliance on IMS Substitution Data Made Him Amply Qualified to Discuss CX 43

In an effort to justify the ALJ's barring Professor Bresnahan from testifying about CX 43 (data on prescription and substitution patterns compiled by IMS Health), Upsher claims that precluding such testimony was justified because it lacked notice that he would testify about this. Upsher, however, ignores the record. ALJ Chappell initially accepted Upsher's claims about lack of notice (*see* Tr. 34:8052), but later amended his ruling, resting only on the voir dire regarding Professor Bresnahan's qualifications:

> I verified that the exhibit, CX 43, is in evidence, so, of course, the witness could read from something in evidence, but my ruling stands, that I wasn't going to allow him to analyze it based on the voir dire of [Upsher counsel] Mr. Gidley. Tr. 34:8122-23.

Upsher's second claim is that Professor Bresnahan could not provide a reliable opinion on IMS substitution data without knowing how IMS would categorize a therapeutic interchange (a change requiring authorization from the prescribing physician). The record shows, however, that Professor Bresnahan's analysis was informed by his knowledge that Schering deemed the IMS substitution data sufficiently reliable to use it in its business planning. *See, e.g.*, CX 13 ("K-Dur 20 enjoys a substitution rate of only 1%" based on IMS National Prescription Audit). Professor Bresnahan testified that his opinion about the lack of substitution away from K-Dur 20 was based on the parties' business documents and the underlying IMS data. Tr. 34:8038-39 (Bresnahan). While Upsher was free to challenge Professor Bresnahan's analysis on cross-

examination, none of its arguments support the ALJ's decision to preclude the witness from offering an opinion concerning this evidence.[56]

C. The ALJ Lacked an Adequate Basis to Exclude Professor Bazerman's Testimony on Risk Preferences

Upsher's defense of the ALJ's exclusion of Professor Bazerman's rebuttal testimony on risk preferences rests on its claim that imposing this extreme sanction here was "automatic and mandatory" by virtue of Federal Rule of Civil Procedure 37(c), relying on *Finley v. Marathon Oil Co.*, 75 F.3d 1225 (7th Cir. 1996). UAB 83-84. But as the Seventh Circuit noted in a later case, "Rule 37 precludes the trial judge from imposing the exclusion sanction unless it finds the party's failure to comply with Rule 26(a) was both unjustified and harmful to the opposing party." *Sherrod v. Lingle*, 223 F.3d 605, 612 (7th Cir. 2000).[57] ALJ Chappell made no finding of prejudice. Indeed, he could hardly find prejudice, having allowed respondents' experts to offer new opinions to counter the views that Professor Bazerman would have offered had he been permitted to do so. Rather, the ALJ imposed the extreme sanction of exclusion solely on the ground that complaint counsel knew risk aversion was an element of respondents' case. Tr. 32:7811-12. In so doing, he abused his discretion. *See, e.g., Sherrod*, 223 F.3d at 613 (district court abused discretion when it imposed sanction of exclusion without finding of harm).

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[56] Upsher's two other complaints – about a misplaced page of an IMS manual marked for identification and that Professor Bresnahan did not review IMS manuals for every year during the period 1996-2000 – could also have been raised on cross-examination. Upsher offers no reason to believe that either of these issues would alter an analysis of CX 43.

[57] After *Finley*, courts in the Seventh Circuit have continued to rely on the four-factor test used to assess exclusion sanctions, discussed at page 86 of our Appeal Brief. *See, e.g., Spearman Indus., Inc. v. St. Paul Fire & Marine Ins. Co.*, 138 F. Supp. 2d 1088, 1094-95 (N.D. Ill. 2001).

D. The Proffered Walgreens Testimony Was Proper Rebuttal

Upsher does not dispute that, prior to the trial testimony of Upsher executive Phillip Dritsas, there had been no claim in this case that pharmacy chains, or in particular Walgreens, had mandated that pharmacists dispense two Klor Con 10s in place of one K-Dur 20.[58] Upsher does not dispute that Mr. Groth from Walgreens would have refuted Mr. Dritsas's testimony. Until Mr. Dritsas testified about Walgreens' policy, we had no reason to call a witness to correct his misstatements. The proffered Walgreens testimony was classic rebuttal evidence.

CONCLUSION

For the foregoing reasons, we respectfully request that the Commission:

1. Vacate the Initial Decision and four rulings by ALJ Chappell that excluded important rebuttal evidence.

2. Adopt complaint counsel's proposed findings of fact and conclusions of law.

3. Reopen the record to take testimony that was improperly excluded, and then issue the order attached to our initial appeal brief.

Respectfully Submitted,

Karen G. Bokat

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Counsel Supporting the Complaint

October 24, 2002

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[58] Although Upsher suggests that the Dritsas testimony regarding pharmacy chain policies was not unexpected because we did not raise an objection, it never explains what objection could properly have been offered.

CERTIFICATE OF SERVICE

I, Patricia A. Allen, hereby certify that on the 24th day of October 2002:

I caused one original and twelve copies of Complaint Counsel's "Reply Brief of Counsel Supporting the Complaint" [Public Version] to be served by hand delivery and one copy to be served by electronic mail upon:

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

I caused a copy of Complaint Counsel's "Reply Brief of Counsel Supporting the Complaint" [Public Version] to be served upon the following person by hand delivery:

Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
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I caused a copy of Complaint Counsel's "Reply Brief of Counsel Supporting the Complaint" [Public Version] to be served upon the following persons by Federal Express:

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