ORIGINAL

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

To: The Honorable D. Michael Chappell
Administrative Law Judge

COMPLAINT COUNSEL'S REPLY BRIEF

[PUBLIC VERSION]

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May 14, 2002

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INTRODUCTION

These facts are undisputed:

1. Schering sued Upsher and AHP, alleging patent infringement.

2. Schering entered into agreements with Upsher in 1997 and with AHP in 1998, settling their litigation.

3. Schering paid Upsher $60 million, and Upsher agreed not to sell its generic K-Dur 20 until September 2001.

4. Schering paid AHP $15 million, and AHP agreed not to sell its generic K-Dur 20 until January 2004.

5. When Upsher finally began selling a generic, it did so at half the price of K-Dur 20.

Given these facts, to find for the respondents one must conclude:

- The plain language of the written agreement between Schering and Upsher doesn't really mean what it says, and thus the entire $60 million Schering paid Upsher was for the Niacor-SR license.

- The judge made Schering pay AHP $15 million, despite Schering's certainty of victory in the patent litigation, and this gives Schering antitrust immunity.

* * * * *

The evidence is in; the trial is over; the record is closed. But the plain language of the respondents' agreements remain unchanged: in return for Upsher's and AHP's agreements to stay off the market with their generic K-Dur 20 products for several years, Schering paid them millions of dollars. Absent generic entry, Schering was able to charge the patients who need K-Dur 20 twice the price of a generic, while still making all the sales.

Respondents' agreements are anticompetitive and violate Section 5 of the FTC Act.

I. SCHERING'S $60 MILLION NON-CONTINGENT PAYMENT TO UPSHER-SMITH WAS NOT FOR THE NIACOR-SR LICENSE

The evidence proves that Schering's $60 million non-contingent payment to Upsher was compensation for a promise not to compete. Although respondents have claimed that this enormous up-front non-contingent payment was merely part of the compensation for the Niacor-SR license, the evidence refutes that claim, and shows that it is a pretext.[1] This assertion is not, as Schering argues, the equivalent of charging the respondents with "fraud," nor does it suggest that the license itself was a "sham." Moreover, the relevant inquiry is not whether the Upsher products were worth $60 million, as Schering indicates.[2] Instead, the factual issue to be decided in this case is whether Schering would have agreed to pay Upsher $60 million in ***up-front non-contingent*** payments for the Niacor-SR license absent Upsher's agreement to stay off the market with its generic version of K-Dur 20. The evidence conclusively shows that it would not have agreed to such a payment absent the settlement.

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[1] Antitrust courts routinely assess whether claimed explanations for allegedly anticompetitive conduct are pretextual, and they do so under ordinary standards of proof applicable in civil antitrust cases. *See, e.g., Eastman Kodak Co. v. Image Technical Servs. Inc.*, 504 U.S. 451, 484 (1992) (where evidence of Kodak's conduct cast doubt on its claimed justification for its challenged conduct, a fact finder could conclude that the justification was pretextual); *JTC Petroleum Co. v. Piasa Motor Fuels, Inc.*, 179 F.3d 1073 (7th Cir. 1999) (evidence of pretextual justifications can support an inference of an unlawful conspiracy).

[2] *See, e.g.*, Schering Brief (US) at 9 ("evaluate the Niacor-SR license opportunity to see if it would be worth $60 million to Schering").

A. The Agreement On Its Face Provides that the $60 Million Payment Was In Consideration for Upsher's Agreement To Stay Off the Market Until September 2001

Respondents largely avoid discussing the very agreement at the heart of this case. And when they do, it is only to try to walk away from its unambiguous terms that facially demonstrate the agreement's anticompetitive nature.

Paragraph 11 explicitly states that the $60 million payment was in consideration for Upsher's agreement to stay off the market until September 1, 2001. CPF 176. But, Mr. Troup testified that Paragraph 11 must be some kind of "typo." Tr. 23:5555-56 (Troup). Schering offers its version of the "intended" meaning of Paragraph 11, and citing New Jersey contract law, suggests that this court may ignore the unambiguous language of the agreement, and instead adopt respondents' self-serving re-interpretation of the agreement that the $60 million payment was only for the Niacor-SR license.[3]

But Paragraph 11 is not the only portion of the agreement which shows the purpose of Schering's payments. Paragraph 3 also directly links Upsher's obligation to abide by the September entry date to Schering's obligation to make the $60 million payment. CPF 171. And the agreement's *force majeure* clause ensures that Schering's obligation to make the $60 million

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[3] Respondents seize upon the "royalty" label used for the $60 million payment to Upsher to support their argument that this payment was for the product licenses. Schering Brief (US) at 11 n. 9; Upsher Brief at 34-35. The antitrust inquiry, however, is not concerned with labels, but rather focuses on the nature and character of the payment. *See In re Yarn Processing Patent Validity Litig.*, 541F.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). Regardless of what it is called, Schering's $60 million payment to Upsher is directly linked by the terms of the agreement to Upsher's agreement to stay off the market with its generic K-Dur 20 product, and is not linked in any way to the development or marketing of the licensed products. CPF 170-75 (terms of the agreement); CPF 247-57 ($60 million payment not contingent in any way to the development or success of the licensing products).

in payments to Upsher would continue even if some act of God made the product licenses it received from Upsher totally worthless, so long as Upsher continued to withhold its generic K-Dur 20 from the market. CPF 180. The terms of the agreement are clear and unambiguous, and there is no room for respondents' contrary interpretation.[4]

B. The Evidence Contradicts Respondents' Claim That The Niacor-SR Transaction Stands On Its Own Two Feet

Schering does not dispute that Upsher demanded a multi-million dollar payment to stay off the market, that Upsher continued to ask for this substantial cash payment throughout the negotiations, and that as part of these discussions Upsher tied its demand to the amount Schering could lose in K-Dur 20 sales if Schering lost the patent infringement suit.[5] In fact, Schering's proposed findings of fact assert each of these points while directly contradicting Mr. Troup's

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[4] *City of Orange Township v. Empire Mortgage Servs., Inc.*, 775 A.2d 174, 179 (N.J. Super. Ct. App. Div. 2001) (citations omitted). The cases cited by respondents reinforce this basic principle of contract interpretation. For example, 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 830, 841 (3d Cir. 1999); *see also Newark Publishers' Ass'n v. Newark Typographical Union*, 126 A.2d 348, 353 (N.J. 1956) (holding that extrinsic evidence is not relevant to the interpretation of a contract when "the meaning of the writing is clear, assessed as an entirety"). Consistent with *Halper* and New Jersey contract law in general, respondents' effort to "chang[e] the writing" of the agreement must be rejected because it is contrary to the plain language of the agreement. *Halper*, 164 F.3d at 841.

[5] *See, e.g.*, SPF 1.8 ("During the course of these May 28 and June 3 meetings, Upsher again suggested that Schering make a payment in connection with a settlement of the patent suit"); 1.14 ("when Upsher's consultant spoke of how much Schering could lose if it lost the patent case, Hoffman perceived the comments as an invitation to pay Upsher to stay off the market"); 1.44 ("the consultant [Upsher] brought was doing some sort of analysis of how much we stood to lose if we lost the lawsuit").

claim that he asked for money to stay off the market only at the first settlement negotiation meeting.[6]

The only dispute then is whether Schering acceded to Upsher's demand. Schering claims it did not, and points to the bargaining position taken by its Associate General Counsel, John Hoffman, during the settlement negotiations in which he told Upsher that Schering would not pay it to stay off the market. But the record evidence contradicts this claim. This evidence, drawn mostly from the agreement itself and the parties' contemporaneous business documents, demonstrates that Schering's $60 million payment was in exchange for Upsher's agreement to the September 2001 entry date, not for the Niacor-SR license as respondents assert:

- The agreement itself explicitly states that Schering's $60 million payment is in "consideration" for Upsher's agreement not to launch any generic version of K-Dur 20 until September 2001, and it directly links Upsher's obligation to abide by the entry date to Schering's obligation to make the payments. CPF 176-81.

- The $60 million payment amount was agreed to before Schering finished its purported evaluation of Niacor-SR, and this amount (discounted for the time value of money) is precisely what Schering estimated to be Upsher's forgone generic K-Dur 20 revenues. CPF 240-44.[7]

- Far from being extraordinarily diligent in its evaluation of the Niacor-SR opportunity, as would be expected after its lawyer has identified antitrust risks and where the amount of up-front cash was unprecedented, Schering's due diligence in the evaluation of Niacor-SR was "strikingly superficial." CPF 373-77.

Respondents look to the presentation paper recommending acceptance of the agreement that was submitted to Schering's Board of Directors to support their position. But this document

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[6] Mr. Troup's version of the negotiations is not credible and should be disregarded. *See* CPF 203-11.

[7] *See also* Complaint Counsel's Brief in Support of Proposed Findings of Fact and Conclusions of Law, at 12-34.

only confirms that Schering's $60 million payment was compensation to Upsher for staying out of the K-Dur 20 market. In fact, this is precisely what Schering told its Board: "[A] prerequisite of any deal would be to provide [Upsher] 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 SP 12 00270, CPF 222.

Respondents focus on another sentence from this document – a key portion of which is stamped redacted – which simply recounts what Schering purportedly told Upsher during the negotiations. CX 338 at SP 12 00268 ("**REDACTED** we informed them [Upsher] that any such deal should stand on its own merit independent of the settlement"). Not only does the non-redacted portion of this sentence fragment say nothing about the actual merits of the Niacor-SR license, but the real mystery is what's behind the redaction – something this Court and the Commission will never know, as Mr. Hoffman conceded:

> Q: Okay, during redirect examination, Mr. Nields read a portion of that document [the Board Presentation], sir, but he took only a portion of that sentence. He didn't read you the full sentence, did he?
>
> A: He read me all of the sentence that's shown there, yes.
>
> Q: Again, sir, he didn't read you the full sentence, because it's not there. Isn't that correct?
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> A: I believe that's correct.
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> * * *
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> Q: At least on this record, we don't know what that statement was. Is that correct?
>
> A: I assume you're correct.
>
> Q: So, for all we know, sir, the first part of that sentence could read, "***Although we are in a position where we must pay for delay***, we informed them that any such deal should stand on its own merit independent of the settlement." From this

record, we can't say whether that's a correct or incorrect statement, right? We just don't know.

A: I believe you do, but from this record, I suppose you don't.

Tr. 15:3580-81 (John Hoffman) (emphasis added).

Finally, Schering argues that because the Board of Directors approved the transaction, it must have determined that the Niacor-SR license stood on its own merit, independent of the patent settlement.[8] This claim, however, is contradicted by the testimony of Schering's Directors. In approving the transaction, the Board relied on the judgment of Schering's senior management, and assumed that "all necessary backup work was done by the responsible people reporting to the top management."[9] The Board certainly was not informed that "all necessary backup work" in this case meant the efforts of a single employee (James Audibert) spending a "little bit more" than one day reviewing Niacor-SR's sales potential. CPF 383, 423. And the Board was not informed that Schering's European operation had already turned down the Niacor-SR licensing opportunity – a fact, at least one Board member thought "[w]e probably should have been aware of." CX 1485 at 33 (Becherer dep).

In short, the evidence shows that the Board considered the proposal for no more than 20 minutes. CPF 220. It did not conduct an independent evaluation of the products that Upsher licensed to Schering, nor was it capable of doing so. CPF 221. And it never even saw the actual agreement. CPF 220. While the Directors may have believed their mission was to evaluate the

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[8] Schering Brief (US) at 10.

[9] CPF 221, 383; CX 1485 at 20 (Becherer dep) (stating that he would expect the management to conduct a "thorough enough investigation that we had a comfort zone with regard to the expectations of the transaction").

transaction "independent of anything else" (Schering Brief (US) at 10), they had neither the experience nor information to do anything but rubber stamp the decision made by Schering's management.

C. The Evidence Confirms that the Payment Was For the September 2001 Entry Date

1. Schering's unprecedented $60 million non-contingent payment

Schering's $60 million non-contingent payment was unprecedented in the pharmaceutical industry at the time, • • • • • • • • • • • • • • • • • CPF 370-72. This fact is not disputed, and Schering's attempts to dismiss its significance by claiming that the size of non-contingent payments do not matter, is neither persuasive nor supported by Schering's general licensing practices.

Product development in the pharmaceutical industry is risky. The parties agree on this point. As Upsher's expert put it: "[M]ore than in most other industries, [in the pharmaceutical industry] 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). Some drug development projects that reach the final stage of clinical trials never receive regulatory approval. Tr. 19:4390 (Lauda). Because of their high failure rate, it is risky to license unapproved products. Tr. 19:4389 (Lauda).[10]

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CPF 294 • • • • • • • • • Most importantly, licensees use contingent payments which are directly linked to the product's success in reaching certain milestones, such as completing a clinical trial or receiving regulatory approval. If the milestone isn't reached, the payment isn't

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[10] *See also* CX 1550 at 128 (Poorvin dep) ("I think everybody knows in this business that filing an NDA does not guarantee approval."); UPF 13-14.

made. CPF 294 [redacted] CPF 300 [redacted] In contrast, non-contingent payments do nothing to manage the inherent risk in pharmaceutical opportunities. These payments come with "no strings attached." CPF 290. Regardless of the product's success or failure, non-contingent payments must be made.

Although Schering now wants to pretend that the distinction between contingent and non-contingent payments is meaningless, the importance of the compensation structure is not lost on a senior Schering licensing executive: 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).[11] And, in fact, that's exactly how Schering always structures its licensing transactions – with the exception of the settlement agreement being challenged in this case. [redacted] CPF [redacted] 326 [redacted]

[redacted]

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[11] *See also* Tr. 29:7122-23 (O'Shaughnessy) (Schering's negotiation expert stated that the first priority in negotiating a deal is to minimize the amount of cash payments because cash is "not leverageable.").

[redacted] In contrast, Schering paid $60 million non-contingent for Niacor-SR.

In addition, in Schering's other licensing deals, the non-contingent fees are modest in comparison to the other payments involved in the transaction. The table below illustrates this point. [redacted][12] [redacted] Tr. at 7:1326 (Levy); CPF 301 [redacted]

[12] [redacted].

Comparison of Non-Contingent Fees to Other Licensing Compensation[13]

	Non-Contingent Fees	Other Licensing Compensation	Other Licensing Compensation as a Percentage of Non-Contingent Fees
Upsher (Niacor-SR)	$ 60 M	$ 10 M	17%
Zonagen (Vasomax)	•	•	•
Centocor (Remicade)	•	•	•
COR (Integrelin)	•	•	•
ICN (Ribavarin)	•	•	•
Neurogen (Dopamine)	•	•	•
Chugai (Maxacalatol)	•	•	•
British BioTech (Marimastat)	•	•	•
AtheroGenics (AGI-1067)	•	•	•

From this table it is clear that the Niacor-SR license is the outlier, a striking exception to Schering's standard licensing practice. Schering offers no rationale as to why, in this case, it abandoned its standard licensing practices, and instead adopted a compensation structure in which non-contingent payments made up the dominant component. By structuring the payments in this manner, Schering did what it never does in a legitimate transaction: it gave up all control over the project and assumed most of the risk of the product's failure. Schering would be "stuck with the payments" even "if the product aborts for some reason." CX 1518 at 59-60 (Morely dep). And when the Niacor-SR project did abort, and Upsher had completely abandoned it, Schering was "stuck" paying Upsher another $32 million. CPF 331-33. As Dr. Levy explained:

[13] CPRF (Schering) 1.351.

[redacted]

Schering defends its substantial up-front payment for Niacor-SR, claiming that it has made substantial cash payments in the past where "that's what it took to get the deal done." Tr. 19:4374 (Lauda). What Schering fails to explain, however, is why it took the largest non-contingent payment in its history to "get the deal done" for Niacor-SR. Niacor-SR was not some exciting novel compound.[14] It was not a product with high revenue expectations, or much up-side potential. Rather, Niacor-SR was a "minor" drug (CPF 334) – an extended-release version of an old compound, with modest sales projections ranging from $45 million to no more than $150 million a year (CX 1044 at SP 16 00047) – the type of pharmaceutical which Schering's Executive Vice President would describe as "not a hugely successful product in the United States." Tr. 19:4434 (Lauda). And this was not a product that had attracted serious interest by other companies. Upsher had spent the better part of six months shopping Niacor-SR to "virtually everybody who is a pharmaceutical manufacturer" outside of the United States. Tr. 28:6931 (Kerr). Most showed no interest, and none offered any payment whatsoever for the non-U.S. rights to Niacor-SR. CPF 781-82.[15]

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[14] *See* [redacted]

[15] *See also* [redacted]

In short, Niacor-SR was not one of those rare licensing opportunities in which it took a substantial up-front payment "to get the deal done." Rather, the only reasonable conclusion one can draw from the evidence is that it took Schering $60 million in up-front, "no strings attached" payments, to get this deal done, because that is the amount Upsher demanded to be paid in return for staying off the market with its generic K-Dur 20 product.

2. Schering's lack of due diligence

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• It concedes that the entire due diligence was conducted by one person, James Audibert from Schering's Global Marketing Department, and that Mr. Audibert's work consisted solely of preparing a commercial assessment and profit and loss statement – or as he described it, a "sales forecast" – of Niacor-SR for territories outside of the United States. Tr. 18:4177 (Audibert).[16] Mr. Audibert's sales forecast took "[m]aybe a little bit more but not – not much more" than one day to complete. Tr. 18:4164 (Audibert). And it is undisputed that in preparing this forecast, Mr. Audibert did not consult with the many internal Schering groups that typically would be involved in evaluating a potential in-licensing opportunity, including Schering's research and development department (CPF 425); regulatory group (CPF 430); intellectual property or patent counsel (CPF 434-35); or European division – the people who would have been responsible for selling Niacor-SR in Europe. (CPF 437-40).

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[16] *See* CX 1484 at 105 (Audibert dep) (describing assignment as "[g]enerating a sales forecast").

As Dr. Levy explained, Mr. Audibert's sales forecast took Schering only "about a third of the way through the preliminary evaluation" of a proposed licensing transaction (Tr. 7:1367-68 (Levy)) – [redacted] CPF [redacted] [17] Schering never began any of the remaining due diligence steps, including the research and development review, regulatory review, intellectual property review, and manufacturing assessment.[18] Despite this limited effort, Schering nonetheless claims that Mr. Audibert was "uniquely qualified to analyze" Niacor-SR and that his "little bit more than" one-day analysis was "all the due diligence that the product required."[19] The evidence, however, does not support Schering's claim.

a. Mr. Audibert is not qualified to conduct due diligence on his own

Mr. Audibert does not have the training nor experience necessary to single-handedly conduct due diligence for Niacor-SR, or any other drug for that matter. He does not have a medical or doctoral degree. CPF 446. [redacted] He had not worked in regulatory

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[17] It is hardly surprising that respondents' attempt to deflect the substantial evidence linking Schering's $60 million payment to Upsher's agreement to stay off the market by attacking the opinions of Dr. Levy, complaint counsel's pharmaceutical licensing expert. Despite respondents' considerable efforts, however, they do nothing to undermine Dr. Levy's opinion – based on his nearly four decades of experience in medicine, academia, and the pharmaceutical industry, and his detailed review of the record – that the $60 million up-front guaranteed payments to Upsher could not possibly have been for the Niacor-SR license.

[18] *Compare* CPF 426-45 (describing Schering's failure to conduct due diligence for Niacor-SR) *with* [redacted]

[19] Schering Brief (US) at 55-56.

affairs in over twenty years, and had no experience with pharmacokinetic studies for niacin. CPF 449-54. Testifying about his work on other Schering in-licensing projects, Mr. Audibert agreed that he "frequently consult[s] people outside global marketing" for guidance on regulatory, clinical and toxicology issues. CPF 447. Yet, Mr. Audibert did not consult with any of these people in preparing his sales forecast for Niacor-SR.

b. Schering's prior evaluation of Niaspan did not obviate the need to conduct due diligence for Niacor-SR

Schering attempts to bolster Mr. Audibert's credentials to handle the Niacor-SR due diligence on his own by referring to Schering's earlier evaluation of another sustained-release niacin product, Niaspan. Mr. Audibert, however, had little involvement in the Niaspan review, participating in only one conference call. CPRF (Schering) 1.88. But more importantly, far from obviating the need for adequate due diligence on Niacor-SR, Schering's experience with Niaspan alerted the company to the potential clinical difficulties of a sustained-release niacin product, and the product's limited market potential:

- A survey of ten medical experts commissioned by Schering during its evaluation of Niaspan explained the historical difficulties in developing and marketing a sustained-release niacin product: "[N]iacin and particularly sustained release niacin, has such a bad reputation among primary care physicians" that successfully marketing of Niaspan will require "compelling data" and strong support from specialists.[20]

- Just eight days prior to Schering's agreement to license Niacor-SR, Martin Driscoll, Schering's Vice President of Sales and Marketing, recommended ending discussions concerning Niaspan, partly, because "Niaspan does not represent a

[20] CX 576 at SP 02715 (internal quotes omitted); *see also id.* at SP 020709 (general practitioners "avoid use of sustained release preparations . . . because of diminished efficacy and concern regarding liver toxicity"), at SP 020717 (data from clinical studies of a sustained release niacin product "will be scrutinized very carefully" as a result of "niacin's history, and especially, the safety issue with sustained release niacin"); *see also* CPF 598-609.

> large-enough opportunity in the marketplace," and that "Niaspan's market opportunity is narrowing even prior to its introduction."[21]

During its Niaspan evaluation, Schering also identified a checklist of issues that would need to be understood "before a deal could be made," including patent status, regulatory labeling, manufacturing capabilities, and product liability. CX 546 at SP 002770. But after identifying this checklist of issues for one sustained-release niacin product, Schering then agreed to pay Upsher $60 million non-contingent for another without doing the due diligence necessary to review or understand any of the issues on the list. CPF 426-44.

c. Mr. Audibert's analysis of Niacor-SR was flawed

It is hardly surprising that Mr. Audibert's commercial assessment of Niacor-SR was flawed in several fundamental ways, given his abbreviated review and lack of qualifications to single-handedly conduct the due diligence. For example, Mr. Audibert assumed Niacor-SR was a "patented sustained-release niacin product." Yet Niacor-SR had no patent protection in Europe at the time of his assessment. CPF 457-58. He described Niacor-SR as a once-a-day drug designed to be administered at bedtime. In fact, Niacor-SR was designed as a twice-a-day product intended to be taken with meals. CPF 460-61. And Mr. Audibert assumed that Niacor-SR would receive regulatory approval, even though he never reviewed the correspondence between Upsher and the FDA, and was not even aware that Upsher was not eligible to receive approval until it conducted an additional pharmacokinetic study. CPF 468-84.[22]

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[21] CX 558 at SP 002719-20.

[22] Mr. Audibert's analysis is flawed in other respects as well, including: (1) the evaluation of the European market fails to take into consideration the appropriate comparator drug for conducting a European pricing analysis, and did not include a country-by-country pricing analysis – something Schering's pricing expert testified he always did in preparing a

Mr. Audibert's assessment of the future sales of Niacor-SR supposedly serves as the basis for Schering's decision to license Niacor-SR. Yet, in preparing this assessment, Mr. Audibert was unfamiliar with even basic features about the product. Although Schering devotes considerable effort in its brief and findings trying to prop up Audibert's "little bit more" than one day sales forecast, in the end, as Dr. Levy put it, Schering's due diligence "just fell dramatically short of any evaluation process that I've encountered for a pharmaceutical of this type." Tr. 7:1341.

3. Respondents' failure to show any serious interest in developing and marketing Niacor-SR

Respondents point to the negative market reaction to Kos's Niaspan as the reason why they failed to show any serious post-deal interest in developing and marketing Niacor-SR. But the evidentiary record shows that the November 1997 Kos stock decline is simply another one of respondents' post-hoc rationalizations.

Even before the decline in Kos's stock price, Schering had never taken any serious steps towards developing Niacor-SR. CPF 717-21. Upsher reduced its commitment to Niacor-SR and decided to proceed with only "minimal activity" towards seeking an NDA in October 1997, one month before the Kos stock decline. CPF 695. The Schering official purportedly appointed as the Niacor-SR project leader had no idea he had been so appointed, and found it "confusing" that his department would undertake these efforts since it was not responsible for seeking drug

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European pricing strategy (CPF 438-39); (2) it assumes Niacor-SR would be used in combination therapy with a statin, even though Upsher had not conducted the clinical studies necessary to obtain approval for this use (CPF 463-64); and (3) it assumes Niacor-SR would reach the European market by early 1999, a date Schering's own pricing expert considered "optimistic." (CPF 465-66).

approval in Europe. CPF 676-78. And when Upsher finally told Schering that it was suspending all development of Niacor-SR, it identified FDA's requirement that Upsher conduct additional clinical work, as its "[f]irst and foremost" reason for doing so. CPRF (Schering) 1.426; CX 1111.

4. Schering's rejection of a similar opportunity for a sustained-release niacin product

During 1997, Schering participated in licensing negotiations with Kos for Niaspan, another sustained-release niacin product.[23] Niaspan was equal to or better than Niacor-SR, in terms of safety and efficacy, and was farther along in the regulatory approval process. CPF 736-63. Kos offered Schering the opportunity to license Niaspan outside the U.S., but Schering rejected this offer to focus on the U.S. rights to Niaspan.[24] Schering then refused to offer Kos an up-front payment for Niaspan rights in the U.S.[25] Yet barely a month later, Schering agreed to make $60 million in up-front payments to Upsher for the non-U.S. rights to Niacor-SR. These facts are not disputed.

Applying basic economic principles ("the revealed preference test") to these facts, Professor Bresnahan concluded that the $60 million non-contingent payment could not have been solely for Niacor-SR. CPF 774-77. Schering does not challenge the economic underpinnings of Professor Bresnahan's revealed preference analysis. Instead, Schering throws out various post-

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[23] SPF 1.89-1.102, 1.108-121, 1.133-1.160 (describing Schering/Kos negotiations); SPF 1.77, 1.193. (Both sustained-release niacin products)

[24] CPF 745-750; CX 1047 at SP 002748 (Schering memo summarizing suggestion that the negotiations focus on the U.S. and "leave ex-U.S. discussions for later").

[25] SPF 1.147 (Schering did not offer Kos an up-front payment); CX 560 at SP 020706 (memo noting end of negotiations for Niaspan, as of July 15, 1997).

hoc rationales to explain away its contradictory approach to two similar licensing opportunities. None of these reasons, however, even begins to explain why Schering would be unwilling to make an up-front payment for the U.S. rights to one sustained-release niacin product (Niaspan), and then turn around a month later and pay $60 million up-front for the less desirable non-U.S. rights to another sustained-release niacin product (Niacor-SR).

- ***Schering argues: The Kos people were difficult to work with***

But Schering's subsequent behavior belies this explanation. . . . . .

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- ***Schering argues: Kos's demands for a large number of "primary details" were burdensome***

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- ***Schering argues: Kos wanted Schering to pay a premium in order to book the Niaspan sales***

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- ***Schering argues: Kos wanted to maintain control of the marketing decisions for Niaspan***

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- ***Schering argues: It was to receive at most half the profits from sales of Niaspan***

But this argument is curious, given Schering's position that a company can use an up-front payment to obtain a better royalty split. Schering Brief (US) at 51. Schering's 50% split of the profits in the Kos deal reflected Schering's refusal to offer any up-front payment. If Schering wanted a more favorable split of the profits, it had the option to assume the risk of the product's failure and offer a large up-front payment. Schering made no such offer. And because Schering refused to offer any up-front payments, Kos rejected Schering's proposal. This evidence shows that Schering was not willing to take the risk of a significant $60 million up-front payment for a sustained-release niacin license (whether Niaspan or Niacor-SR) and confirms that Schering would not have entered into such a license "independent of the [patent] settlement" (CX 338) and

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5. No other company besides Schering offered any non-contingent payment to Upsher for Niacor-SR

Prior to entering into the agreement with Schering, Upsher shopped the European rights for Niacor-SR to "virtually everybody who is a pharmaceutical manufacturer" outside the United States. Tr. 28:6931 (Kerr). Many of the companies rejected the opportunity out of hand, citing

Niacor-SR's "limited commercial potential," "doubtful . . . commercial prospects," or "known side effects." CPF 786-97. Of those companies that expressed some interest, none offered any up-front payment of any size. In fact, none of these "interested" companies made any offer whatsoever for the Niacor-SR rights. CPF 781, UPF 405-420.[26] This evidence shows that Schering's agreement to make $60 million in up-front payments was far out of line with the market value of Niacor-SR license, as assessed by numerous experienced, sophisticated pharmaceutical companies. CPF 807-808.

Respondents do not dispute these facts, and all they can muster to undermine the economic conclusion of the "market test" is the testimony that one company may value a licensing opportunity differently than another. Schering Brief (US) at 19. While this is almost certainly true, is it really plausible that Schering could value Niacor-SR as being worth $60 million in non-contingent payments while every other company that looked at this opportunity didn't even offer a buck?[27]

The respondents also attempt to provide a market test of their own, relating the value of Upsher's Niacor-SR to the prior market capitalization of Kos. Upsher Brief at 30; Schering Brief (US) at 20. But this analogy fails for several reasons. First, Kos's stock price was not based

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[26] . . . . . .

[27] Upsher's criticism of Professor Bresnahan's market test, which is based on the supposed ongoing interest of several companies, only reinforces the inadequacy of Schering's due diligence. Upsher Brief at 29. Upsher began its marketing efforts of Niacor-SR in January 1997. Several companies had shown some interest. But even after six months, none had made an offer. Yet, Schering was ready with its $60 million non-contingent offer after a "little bit more" than one day's work. It just doesn't add up.

solely on the perceived value of Niaspan, as would be required under respondents' "market test." Rather, the value of Kos stock was based on the company's overall long-term ability to discover and develop new compounds, as well as the many other products in Kos's research and development pipeline. Kos's prospectus for its initial public offering identified the various products under development at that time, including "three other once-a-day, controlled release cardiovascular products" (USX 21 at AAA 0000055), as well as "five aerosolized inhalation pharmaceutical products." *Id.* Kos also planned to submit "an abbreviated new drug application ('ANDA') for its CFC albuterol in 1997" (*Id.*), and it had formed a joint venture with Fuisz Technologies "for the development of up to six products using Fuisz' proprietary microsphere formulation technology." *Id.* Respondents make no effort to evaluate what portion of Kos's stock price reflected the Niaspan prospects, and what portion was attributable to Kos's other ventures. Tr. 27:6612-14 (Kerr).

In addition, the market analysts' sales projections for Niaspan were overly optimistic, as Schering's internal management recognized. While market analysts had projected $250 million in annual Niaspan sales, Mr. Driscoll observed that Schering "do[es]n't necessarily share that view." He "estimate[d] peak year sales for Niaspan" at only "$134 million." CX 558 at SP 002719; SPF 1.314; CPRF (Schering) 1.310. The investment analysts who were publicizing these inflated Niaspan sales forecasts had ownership interests in Kos as a result of underwriting Kos's initial public offering. CPRF (Schering) 1.190. Accordingly, Kos and the investment analysts had a strong incentive to "grossly overstate [Niaspan's] potential earnings" in order to "pump up their stock price." Tr. 9:1856 (Levy); CPRF (Schering) 1.310; *see also* Tr. 27:6616

(Kerr). Yet Dr. Kerr admitted that he based his market valuation of Niacor-SR on these unreliable sources. Tr. 27:6617-20.

II. THE EVIDENCE ESTABLISHES THE HARM TO COMPETITION FROM THE CHALLENGED AGREEMENTS

Since Schering's $60 million payment was not for Niacor-SR, the inescapable conclusion is that Schering paid Upsher to delay its entry until September 2001. Of course, no one can know exactly when Upsher would have entered, but Schering plainly thought that entry by Upsher before 2001 was sufficiently likely that it paid $60 million to protect against that possibility. After the June 1997 agreement with Upsher, however, K-Dur 20 sales had "a new lease on life." CX 20 at SP 004040 (1998 K-Dur Marketing Plan). And Upsher's conduct and statements prior to the agreement show it believed it was likely to launch its product well before 2001. CPF 85-165.

There can be little doubt that the $60 million payment was, like the price fixing agreements settling patent disputes condemned in *United States v. Masonite*, 316 U.S. 265, 281 (1942), "a powerful inducement to abandon competition." The payment means that, in agreeing to stay off the market for several years, Upsher was not simply acceding to the force of Schering's patent. The payment thus fundamentally altered the competitive process that underlay the parties' decisions about settlement. And that harm to the competitive process injured consumers. While it is impossible to know for certain whether and to what extent generic competition was actually delayed, the $60 million payment surely delayed entry relative to what respondents expected at the time they entered into the agreement.

Neither Schering nor Upsher appears to dispute that paying a generic entrant in exchange for an agreement to stay off the market would distort the generic firm's ordinary incentives about when it would enter and compete. And neither has suggested that – absent the patent dispute – the challenged agreements would be anything other than obvious *per se* violations. Indeed, it is well accepted, as cases such as *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49 (1990) demonstrate, that paying a potential competitor to withhold competition is *per se* unlawful, even when that competitor's entry into the market is uncertain. While respondents rest their defense on the fact that the agreement settled patent litigation, they never explain why uncertainty about whether a generic firm will prevail in patent infringement litigation should be treated differently than other types of factors that make a potential competitor's entry uncertain. Nor do they cite any authority for the proposition that a patent holder is entitled to bribe a potential competitor to stay off the market.

Instead, respondents argue that: (1) the agreements' provision for entry prior to patent expiration means they cannot be condemned as *per se* unlawful (a contention we refute in our initial brief and Section V of this brief); and (2) the rule of reason requires complaint counsel to prove that Upsher would have entered earlier absent the payment. Upsher makes various claims that entry earlier than 2001 was unlikely, based on self-serving, post-hoc arguments that are inconsistent with its position prior to this litigation. *See* CPRF (Upsher) 711. Schering urges an inquiry into the merits of the patent cases that, as we explained in our prior briefs, is irrelevant and provides no meaningful information.[28]

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[28] *See also* Appendix to this reply brief.

At the heart of respondents' arguments is a misconception of the proof required under the rule of reason. Moreover, their criticism of Professor Bresnahan's conclusion that the payments to stay off the market were anticompetitive rests on a misreading of his analysis.

A. The Rule of Reason Inquiry Focuses on Likely or Probable Effects

The Supreme Court's early articulation of the rule of reason in *Chicago Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918), made it clear that rule of reason analysis considers a restraint's "actual or probable" effects on competition:

> The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable.

Neither an anticompetitive intent nor a conscious desire to violate the law is required to prove a rule of reason violation. Courts may consider evidence of the parties' purpose in order to "interpret facts and predict consequences." *Chicago Bd. of Trade*, 246 U.S. at 238. That is because, as the Areeda and Hovenkamp treatise observes, "in cases of ambiguity we presume that the defendants, who are in the best position to know their business, are also rational actors. As a result, knowledge of their own expectations can aid a tribunal in determining whether the likely effects of a restraint are competitive or anticompetitive."[29] But just as an anticompetitive purpose

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[29] XI Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶ 1912g at 298 (1998).

will not condemn a restraint that appears unlikely to impair competition, a lack of such intent will not save one with the opposite tendencies.[30]

Upsher ignores these principles, and continues to quote language from a Ninth Circuit case to suggest that the rule of reason requires a showing of anticompetitive intent (Upsher Brief at 41), a proposition that is plainly contrary to well-established Supreme Court law. Schering, on the other hand, tries to turn the law's emphasis on competitive effects into a defense of its claim that this court must "objectively" determine the merits of the patent infringement cases. *See* Schering Brief (ESI) at 28-30. But as we discussed in our prior brief, the test that Schering proposes is not required by the antitrust laws, and it is neither objective nor feasible to carry out in any meaningful way – even if it included the parties' internal assessments of the case (which they have refused to disclose).

With respect to proving effects, respondents offer up numerous quotes from cases stating that the rule of reason requires proof of "actual anticompetitive effects."[31] But none of these cases hold that the rule of reason requires proving what would have happened "but for" the challenged conduct. Such proof is always impossible, because the court cannot recreate the "but

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[30] *NCAA v. Board of Regents of the Univ. Of Okla.*, 468 U.S. 85, 101 n.23 (1984) (though the defendant's motives "must be accorded a respectful presumption of validity, it is nevertheless well settled that good motives will not validate an otherwise anticompetitive practice") (citations omitted); *see also Chicago Bd. of Trade*, 246 U.S. at 238; *United States v. United States Gypsum Co.*, 438 U.S. 422, 466 n. 22 (1978) (in a civil antitrust action no anticompetitive intent need be proved – proof of an anticompetitive effect is sufficient).

[31] For example, at page 36 of Schering's Brief (ESI), it quotes language from *Levine v. Central Fla. Medical Affiliates, Inc.*, 72 F.3d 1538, 1552 (11th Cir. 1996), that "[p]roof of . . . intent [to restrict competition] would not relieve [plaintiff] of the necessity of . . . proving an actual detrimental effect on competition." On the same page of the same case, however, the court states: "rule of reason analysis is concerned with the actual or likely effects of defendants' behavior."

for" world. The very reason we cannot know what would have happened in the patent case is that respondents agreed to abandon the patent litigation and exchange payments for a promise to stay off the market.

For example, in *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (per curiam), the court squarely rejected the suggestion that the antitrust laws require proving the "but for" world. As the court noted, "neither plaintiffs nor the court can confidently reconstruct a product's hypothetical technological development in a world absent the defendant's exclusionary conduct." *Id.* Thus, in applying the rule of reason under Section 2 of the Sherman Act, the court held there was no need to prove that Java or Netscape would have developed into a viable substitute for Microsoft's operating system. Instead, in an action for injunctive relief, the court could infer anticompetitive effects when "a defendant has engaged in anticompetitive conduct that 'reasonably appear[s] capable of making a significant contribution to . . . maintaining monopoly power.'" 253 F.3d at 79, *quoting* III Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 651c at 78 (1996).

The same court, in *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001), considered what inference about likely effects could properly be drawn from an agreement similar to the one challenged here. The case involved a claim by Biovail, a subsequent ANDA filer for generic Cardizem CD, that the agreement between brand name drug maker Hoechst and would-be generic entrant Andrx (the one condemned as *per se* unlawful in the *Cardizem CD* case)[32] unlawfully blocked its entry into the market. The court reversed the lower court's ruling

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[32] *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682 (E.D. Mich. 2000), *appeal docketed*, No. 00-2483 (6th Cir. Dec. 19, 2000).

that Biovail could not establish antitrust injury causally related to the agreement, because its product had not yet received FDA approval and there was no assurance that it would enter the market if approval were granted. It held instead that, in a suit for equitable relief, Biovail need only show a threatened injury. *Id.* at 806, 808. Moreover, the court rejected the claim by Andrx that a fact finder could not infer that the payment delayed its entry: "One can fairly infer . . . that but for the Agreement, Andrx would have entered the market." *Id.* at 809. The court noted that Hoechst's ten million dollar quarterly payments were presumably in return for something that Andrx would not otherwise do, that is, delay marketing of its generic. *Id.* at 813.

Andrx v. Biovail confirms that it is proper to infer from the fact of the substantial payments made to Upsher-Smith and AHP to secure their agreement to stay off the market – that at the time they were entered into, the agreements were likely to delay entry by these potential competitors. Even if subsequent events meant that the effects likely to result from the agreement did not materialize – for example, if Upsher's plant had burned down, if it had failed to obtain necessary financing or regulatory approvals, or for some other reason – that would not alter the conclusion that at the time the agreement was entered into it was likely to cause substantial competitive harm.[35] Similarly, uncertainty about whether Upsher and AHP would have ultimately prevailed in the patent cases does not undermine the anticompetitive nature of conduct that, at the time it was entered into, was likely to delay generic entry. Given the obvious effect that large payments to stay off the market would have on a generic firm's decision about when to

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[33] *Microbix Biosystems, Inc. v. BioWhittaker, Inc.*, 172 F. Supp. 2d 680, 694-95 (D. Md. 2000), *aff'd on other grounds*, No. 00-2262, 2001 WL 603416 (4th Cir. Jun. 4, 2001) (an exclusive supply agreement that created a barrier to competition at the time it was entered into could be condemned under the rule of reason, even though subsequent action by the FDA made it impossible for the target of the exclusionary conduct to enter the market in any event).

enter and compete, the challenged agreements in this case are "likely enough to disrupt the proper functioning of the price-setting mechanism of the market," that they may be deemed anticompetitive even without proof that they actually "resulted in higher prices . . . than would occur in [the conduct's] absence." *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 461-62 (1986). Indeed, as the D.C. Circuit observed in *Microsoft*, to rest antitrust liability on a requirement that plaintiffs "reconstruct the hypothetical marketplace" absent the challenged conduct would merely encourage "more and earlier anticompetitive action." 253 F.3d at 79.

B. Professor Bresnahan's Analysis Is Based on Sound Economics Applied to the Record Evidence

Respondents' attempts to ignore the documentary evidence in this case are evident in their attack on Professor Bresnahan's analysis. Antitrust analysis begins with identification of a theory of competitive harm, and then looks to see whether the evidence supports the conclusion that the theory applies in the particular circumstances of the case.[34] Professor Bresnahan did both. Relying on well-established economic principles, he articulated a sound theory of the likely harm from the agreements and then applied it to the evidence in this case. Respondents' claim that he "over-relied" on the parties' incentives to share profits from delayed generic entry simply ignores the evidence they find inconvenient. The purported conflicts between Professor Bresnahan and Professor Bazerman are illusory.

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[34] *See, e.g., California Dental Ass'n v. FTC*, 526 U.S. 756, 775 n.12 (1999) (prima facie case under the rule of reason requires sound theoretical basis and evidence that supports application of the theory in the particular market circumstances).

1. Professor Bresnahan relied both on the existence of incentives to engage in anticompetitive conduct and evidence that respondents acted pursuant to those incentives

Both respondents make a great to do in their briefs about Professor Bresnahan's reference to the parties' incentives in his analysis.[35] But one of the lessons of modern antitrust analysis is that courts need to consider just such incentives, to ensure that antitrust cases make economic sense.[36] Thus, Professor Bresnahan, as any economist would, took the parties' economic incentives into account when he analyzed their agreement and the surrounding conduct and circumstances. While Schering and Upsher draw quotes from cases upholding summary judgment for defendants, those cases concerned questions about whether competitors were engaged in unilateral rather than concerted conduct, or whether an individual competitor could be tied to a broader conspiracy.[37] The Supreme Court has expressed concern about situations in which mistaken inferences would threaten to "deter or penalize perfectly legitimate conduct," especially in vertical relationships between manufacturers and dealers. *See Monsanto Co. v.*

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[35] *See* Schering Brief (US) at 4-5; Upsher Brief at 30-31.

[36] *See, e.g., Matsushita Electric Industrial Co., v. Zenith Radio Corp.*, 475 U.S. 574, 596-97 (1986) (where there is no rational economic motive to conspire, and there are other, equally plausible explanations for the defendants' conduct, their conduct does not give rise to an inference of conspiracy).

[37] *See In re Baby Food Antitrust Litig.*, 166 F.3d 112, 134-35 (3d Cir. 1999) (motive to engage in conspiracy because defendants could profit thereby by itself did not permit inference that allegedly parallel prices were result of price fixing agreement rather than unilateral conduct; economist's affidavit was based on assumption that defendants had agreed to conspire, and he "never made any reference to the evidence in this case"); *Serfecz v. Jewel Food Stores*, 67 F.3d 591, 600-01 (7th Cir. 1995) (no agreement between shopping mall owners and tenant to eliminate competing mall could be inferred from conduct that was entirely consistent with unilateral action); *In re Citric Acid Litig.*, 191 F.3d 1090, 1093 (9th Cir. 1999) (evidence insufficient to permit inference that Cargill participated in a price fixing conspiracy engaged in by other industry members).

Spray-Rite Service Corp., 465 U.S. 752, 763, (1984). These concerns about erroneously inferring the existence of an agreement solely from circumstantial evidence do not apply when there is direct evidence of concerted action.

Professor Bresnahan, however, did not use the parties' incentives to infer the existence of an agreement between the parties based on parallel conduct. Instead, he considered their incentives, along with other evidence, to assess the purpose and likely effect of an agreement for which there is undeniable direct evidence, notably a written agreement between the parties that links Schering's $60 million non-contingent payment to Upsher's obligation to stay off the market. Based on the evidence – including documents such as the memorandum to the Schering board of directors recommending approval of the Niacor-SR license and the "Executive Summary" – he concluded that respondents acted on their incentives to reach an agreement to delay entry. •

Schering incorrectly suggests that Professor Bresnahan's analysis was based on the view that the mere presence of a "reverse" payment in a settlement would establish that the settlement was anticompetitive. *See* Schering Brief (US) at 72-73; Schering Brief (ESI) at 12-13.[38] But

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[38] Schering uses this mischaracterization of Professor Bresnahan's views to suggest that he offered a novel theory, citing an article that states the presence of a reverse payment by itself is insufficient to show that a patent settlement is anticompetitive. Richard J. Gilbert and Willard Tom, *Is Innovation King at the Antitrust Agencies? The Intellectual Property Guidelines Five Years Later*, 69 Antitrust L.J. 43 (2001). It is curious that Schering chose to rely on this article,

Professor Bresnahan's analysis plainly considered not merely the presence of such a payment, but also what the payment was for. CPF 1132; Tr. 3:421-22 (one considers whether a payment was made for delay because delaying or reducing the threat to monopoly power is anticompetitive). The absence of any other plausible explanations for the payments (CPF 1201-1208), along with other evidence including the parties' incentives, leads to the conclusion that the agreement was for delayed entry.

2. The purported conflict with Professor Bazerman is illusory

Schering suggests that Professor Bresnahan's views are in conflict with the testimony of complaint counsel's negotiation expert, Professor Max Bazerman, that parties in negotiations often deviate from the economic model of rationality. Schering Brief (ESI) at 12-13. In fact, Professor Bazerman's testimony provides further support for Professor Bresnahan's conclusions. First, Professor Bazerman specifically addressed and rejected the suggestion that his research on negotiation and decision biases would draw into question Professor Bresnahan's conclusion that the $60 million payment to Upsher was for delayed generic entry.[39] He found no reason to believe that the economic model was not an accurate predictor in these circumstances.

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because Gilbert and Tom specifically address the allegations in this case, as well as those of the Commission's complaints against Abbott/Geneva and Hoechst/Andrx, and conclude: "Based on the allegations in the public record materials, *these agreements appear to be anticompetitive arrangements to eliminate competition and to divide the monopoly profits of successful branded drugs*." *Id.* at 76 (emphasis added).

[39] Tr. 36:8504 (Bazerman):

> Q: Now assuming that the $60 million payment to Upsher was not for Niacor and assuming that Professor Bresnahan's analysis of monopoly power is accurate, do you see anything in the literature on these biases that you've researched that would lead you to a conclusion that the payment was not for delay?
>
> A: I do not.

Second, Professor Bazerman described the effect of "self-serving biases" and its implications for respondents' claims that Professor Bresnahan overlooked the parties' incentives to comply with the law. Professor Bazerman explained that a payment for delay need not involve intentionally corrupt behavior. Instead, honest business people might pay for delayed generic entry, but be convinced that they have not done so because of self-serving bias – the tendency of individuals to see the world the way they would prefer to see it. CPF 1263; Tr. 36:8519-20 (Bazerman). Professor Bazerman also explained that self-serving bias is more likely to occur when the relevant legal rule is ambiguous. Tr. 36:8521-22; CPF 1258. As a result, Schering's claim that, at the time of the challenged agreements, the law concerning the antitrust implications of patent settlement was "undeveloped" is just an additional reason that incentives to obey the law would be unlikely to overcome incentives to earn the greater profits that could be achieved through collusion. Professor Bazerman's research thus reinforces Professor Bresnahan's conclusion.

III. RESPONDENTS OFFERED NO PLAUSIBLE PROCOMPETITIVE JUSTIFICATION

Respondents bear the burden of establishing a procompetitive justification for the challenged agreements (*see NCAA,* 468 U.S. at 113), and they have failed to do so.

A. Establishing a Certain Date for Generic Entry Does Not Justify the Agreement

Both Upsher-Smith and Schering contend that their agreement is procompetitive because it set a certain entry date, prior to patent expiration. Schering makes the same claim for its agreement with AHP. These claims are neither plausible nor even cognizable justifications for the agreements.

According to Upsher-Smith, "[c]onsumers were better off gaining the certainty of the settlement, rather than gambling on the patent litigation." Upsher Brief at 50-51. But Upsher's argument that the certain entry date was procompetitive simply because it might have lost the litigation and been barred from entry until 2006 plainly proves too much. For under this logic, any payment for delayed entry would be lawful, even if it provided for entry only a day before patent expiration. And Upsher's protestations that, absent the certainty of the entry date, it would not have made the necessary investments or otherwise been in a position to launch its product before September 2001 are implausible, given its statements and behavior prior to the settlement. This is merely post-hoc rationalization that is contradicted by the more reliable evidence contained in the Upsher business documents prepared prior to the agreement. *See* CPF 118-162; 1400-1404. In any event, as we noted in our opening brief, the suggestion that Schering paid Upsher $60 million to enable Upsher to enter earlier than it could have through litigation is wholly implausible.

Schering's argument that the settlement benefitted consumers begins with the simple proposition that the agreement provided "known and certain" generic competition, while "[c]ompetition which might have resulted from litigation is unknown and uncertain." Schering Brief (US) at 74. But Schering's economic expert, Dr. Willig, testified that just because a settlement agreement guaranteed entry before patent expiration does not make it procompetitive. Tr. 29:7243 (Willig). So Schering's claim that the settlement was "a very good deal for consumers" ultimately depends on its purported showing that the settlement with Upsher "fairly reflected the relative strengths of the parties' positions on the merits [of the patent infringement

case]." *Id.*[40] In the case of the AHP settlement, Schering goes even further, and claims that it would have won the patent case. Schering Brief (ESI) at 26. As we discussed in our initial brief, however, the evidence that Schering offered at trial provides no meaningful information that would help a court assess the competitive effects of the agreement. The testimony that was offered is subjective opinion, based on information so limited that one cannot reliably assess the parties probabilities of success, and in any event it cannot be calibrated with sufficient accuracy to permit any comparison between the settlement and the expected outcome of the patent litigation. Moreover, as we explain in the Appendix to this brief, Schering has failed to demonstrate that it would have won either case and has failed to prove its assertions about the relative merits of the parties' positions in the patent litigation.

In any event, respondents are not entitled to justify their anticompetitive agreement on the ground that consumers should prefer certain entry, even though achieved through payments that distort the competitive dynamics between the parties. The results of the competitive process are necessarily uncertain, but the antitrust laws rest on the fundamental premise that this process will produce the best results for consumers. Respondents' claim that consumers were better off with the certainty of entry is not a cognizable justification for their agreements.[41]

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[40] Schering also suggests that, even if Upsher had prevailed, it would not have been able to market its product until at least mid-1999, given the likely time for resolution of any appeals. Schering Brief (US) at 74. •. Indeed, it would suggest that Schering did not just make up for Upsher's lost revenues, but actually paid a substantial premium over what it thought Upsher was likely to earn had it prevailed in the suit – and would simply reinforce the conclusion that the payment was anticompetitive.

[41] *See, e.g., Catalano, Inc. v. Target Sales, Inc.*, 446 U.S. 643, 647 (1980) ("It is no excuse that the prices fixed are themselves reasonable").

B. Upsher's Other Purported Procompetitive Benefits Do Not Justify A Payment for Delay

A challenged restraint on competition must be "tailored" to serve a legitimate procompetitive purpose. *NCAA*, 468 U.S. at 119. Upsher's various other proffered procompetitive benefits suffer from a common flaw: they are not reasonably related to the unlawful conduct challenged here. The claimed benefits flow from a settlement of litigation or the granting of licenses, neither of which is challenged in this case. None justify payments to stay off the market.

Avoiding patent litigation over Klor Con M10: The patent issues concerning Klor Con M10 and Klor Con M20 are the same. The '743 patent relates to the coating material on the potassium chloride crystals and is not limited to any particular dosage strength. CX 12 ('743 patent). Since Upsher used the same coating material for Klor Con M10 as for Klor Con M20 (CPF 1406), the products raised precisely the same infringement issue.

Upsher provides no explanation why Schering would need to pay Upsher in order to obtain an agreement to resolve the infringement claim as to Klor Con M10 in accordance with the resolution of the claim relating to Klor Con M20. Nor has Upsher explained why a decision in the litigation over Klor Con M20 would not have resolved the issue for the M10 product as well. Any benefit from avoiding litigation over Klor Con M10 is neither logically connected to the payments nor significant relative to the consumer harm from delayed K-Dur 20 generic competition.

Overseas distribution of six Upsher-Smith products: Since Schering's $60 million in non-contingent payments to Upsher was not for the licenses, any procompetitive benefits flowing

from the licenses cannot justify the agreement to exchange payments for a promise to stay off the market. The agreement was plainly not reasonably necessary for the parties to enter into a procompetitive arrangement for distribution of Upsher's products.

Savings in litigation costs could fund procompetitive R&D and marketing activities: Every settlement allows the parties to avoid litigation costs. Respondents have not demonstrated that payments to stay off the market are reasonably necessary to achieve a settlement. And even if respondents would not have settled on any other terms, any possible benefits to competition that might arise from the parties' avoiding litigation costs are dwarfed by the harm from delayed generic entry.

The payments were a return on Upsher's R&D investment: This proffered justification fails because the evidence shows that the $60 million payment was made to secure Upsher's agreement to stay off the market and *not* for the licenses conveyed to Schering.

Upsher's entry resulted in two other generic K-Dur 20 products, Qualitest and Warrick: Since the purpose and likely effect of the agreement was to delay Upsher's entry, any products available as a result of Upsher's launch of its product were therefore delayed as well. Moreover, since Qualitest is a distributor for Upsher and Warrick is a Schering subsidiary, these companies added no new competitors to the market.

Acceleration of expiration of the Hatch-Waxman 180-day exclusivity period: If the payments to stay off the market had the likely effect of delaying entry, then they would necessarily delay, rather than accelerate, Upsher's triggering of the Hatch-Waxman exclusivity period. Nonetheless, Upsher asserts that the agreement accelerated triggering of the exclusivity period, under the following reasoning: (1) absent the payments, there would have been no

settlement; (2) Upsher would have lost the patent suit; and (3) Upsher would have maintained its exclusivity rights. Upsher's argument thus rests on a series of assumptions, each of which is necessary for its argument to hold up, and none of which has been established in this proceeding. We note that the assumption that Upsher would have retained its exclusivity rights if it lost the patent case is an especially thin reed upon which to base a claim of plausible procompetitive benefit, because neither the FDA nor the courts have ever adopted the position that a losing first ANDA filer retains exclusivity rights. The two FDA experts in this proceeding had different opinions on how a court might come out on the question today, and complaint counsel's expert, Mr. Hoffman (upon whom Upsher relies), made it clear that his opinion that a losing first ANDA filer would retain its exclusivity rights is based on his view of the law as it stands today – not at the time of Upsher's June 1997 agreement with Schering.[42]

In any event, the notion that Schering and Upsher entered into their agreement in order to avoid the risk that other potential generic entrants would be blocked from entry is plainly implausible. As Professor Areeda observed, "we would not expect a group of rational profit-maximizing firms to enter into a restraint whose purpose was to make entry into their market easier."[43]

Conserving judicial resources: All settlements save judicial resources, and settlements themselves are not inherently problematic from an antitrust perspective. But no court has ever held that such savings can justify an anticompetitive settlement agreement. Moreover, as we

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[42] *See* Tr. 10:2287-88 (Joel Hoffman); Tr. 28:6967-68 (Safir).

[43] XI Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 1912h at 301 (1998).

discussed in our opening brief, there are numerous cases holding patent settlement agreements unlawful.

IV. SCHERING'S DEFENSE OF ITS AGREEMENT WITH AHP

A. The Magistrate's Involvement Creates No "Presumption of Lawfulness"

Aside from legal arguments that mirror its defense of the Upsher agreement, Schering's defense of its agreement with AHP rests primarily on its assertion that the involvement of the magistrate judge in the settlement discussions gives the agreement a "presumption of lawfulness." Schering Brief (ESI) at 1, 9. This claim has no basis either in law or in the facts of this case.

Schering offers no legal authority for its claimed "presumption," and none exists. The most Schering manages is a "*cf.*" cite to a case involving formal court review of a class action settlement. In that case, *Robertson v. NBA*, 556 F.2d 682, 686 (2d Cir. 1977), the court held that class members in a properly certified antitrust class action suit could not overturn approval of a settlement on the ground that it perpetuated the allegedly unlawful conduct. That result arises, however, not because the court's approval of the settlement creates any presumption of lawfulness, but rather because the whole purpose of the settlement is to avoid a mini-trial on the merits.[44] The court's review of any alleged antitrust issues is strictly limited. Thus, even in the context of formal court review of a class action settlement, there would be no presumption that the settlement is free from antitrust concern, and Schering cites no case recognizing such a presumption. 556 F.2d at 686.

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[44] *Robertson*, 556 F.2d at 686 ("a court in approving a settlement should not in effect try the case by deciding unsettled legal questions").

And in any event, Schering's settlement agreement with AHP was not a class action suit, and did not receive court review and approval. Indeed, Schering's attempt to equate the magistrate's brokering of a settlement with court approval is plainly off the mark. The magistrate had no power to disapprove a settlement agreed to by the parties. The suggestion that a magistrate's knowledge, or even endorsement, of the settlement terms would alter the ordinary antitrust analysis that focuses on the competitive impact of a restraint is unfounded.

B. The Size of Schering's Payment to AHP Relative to its Total K-Dur 20 Profits Confirms the Anticompetitive Nature of the Payment

Schering's suggestion that the payment to keep AHP off the market was not anticompetitive because it was only a small fraction of Schering's total profits for K-Dur 20 does not advance its defense.[45] The key issue is whether the payment to stay off the market was sufficient to induce AHP to abandon the litigation and agree to forestall entry. The parties' written agreement shows that it plainly was.

The fact that AHP received less money than Upsher is not surprising, given the greater degree of uncertainty about when AHP might be able to launch its product. AHP was potentially blocked from entry by virtue of Schering's agreement with Upsher, and it had not yet obtained tentative FDA approval of its product. AHP's expected profits were therefore less than what it would earn had its entry been certain, and to prevent entry, Schering needed only to pay AHP's expected profit. CPF 1163-64.

That Schering was able to induce AHP not to compete by means of a payment that represented only a small portion of its K-Dur 20 profits is precisely the point we have made

[45] *See* Schering Proposed Conclusions of Law in Connection with its Settlement with ESI-Lederle, Inc. at ¶ 4d; Schering Brief (ESI) at 13 n.15.

throughout this proceeding: Schering's incentives to pay AHP and Upsher to ensure they did not enter the market were extremely powerful, because by sharing only a portion of its K-Dur 20 profits Schering could eliminate the risk that the generics might enter. Both Schering and AHP were well aware that such entry, if it occurred, would cause Schering's K-Dur 20 profits to plummet. Even if, as Schering contends, it had a stronger infringement case against AHP's product than it did against Upsher, the risk of a loss in that case remained, and Schering does not seriously contend otherwise.[46]

V. THE AGREEMENTS ARE PER SE UNLAWFUL

Respondents' arguments that the payments to stay off the market are not *per se* unlawful rest on the fact the agreements arose in the context of patent settlements. That fact alone, however, does not make *per se* treatment inapplicable.[47] While Schering is correct that settlements of patent disputes are not, as a class, *per se* unlawful, it is equally clear that neither do they automatically fall outside the *per se* rule, notwithstanding that all settlements have some "redeeming virtue." Schering Brief (US) at 62. And, as we discussed in our initial brief, respondents' invocation of Professor Hovenkamp's treatise (Schering Brief (US) at 60-61) is unavailing, because it expressly acknowledges the various cases holding patent settlements *per se* unlawful. Indeed, a recently published treatise on intellectual property and antitrust co-authored by Professor Hovenkamp (and cited in Schering's brief in the monopoly power discussion),

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[46] In the Appendix to this brief, we discuss the flaws in Schering's contentions about the likely outcome of the patent infringement case against AHP. Schering's suggestion that at the time of the agreement in principle AHP believed it would lose the patent litigation (Schering AHP Brief at 19) is based solely on testimony given in anticipation of this antitrust challenge to the agreement.

[47] *See, e.g., United States v. Masonite Corp.*, 316 U.S. 265, 281-82 (1942).

discusses patent-holder Hoechst's agreement to pay Andrx, the would-be generic entrant, to stay off the market as a naked horizontal market division. II Herbert Hovenkamp, Mark D. Janis, & Mark A. Lemley, *IP and Antitrust* (2002) § 33.2b at 33-14 ("As a general proposition, in the absence of joint production, an agreement by one firm to stay out of its rival's market in exchange for payments of money is unlawful per se").

This is not to suggest that the patent context is to be ignored. Rather, the analysis must focus, as the Supreme Court instructed in *Broadcast Music, Inc. v. CBS, Inc.*, 441 U.S. 1, 20 (1978), on the likelihood of competitive harm and the presence of plausible arguments that the conduct was "designed to increase economic efficiency and render markets more, rather than less, competitive." But the proof that the agreements here involved payments to a potential competitor to stay off the market, and the absence of any plausible procompetitive explanations for the payment, mean the agreements are unlawful *per se*.

While the conclusion that the challenged agreements are *per se* unlawful does not depend on the decisions in the *Cardizem* and *Terazosin* cases,[48] Schering's attempt to dismiss these decisions on the theory that there was no provision to allow entry before patent expiration – is incorrect. The agreement challenged in *Cardizem* guaranteed Andrx the right to enter with its generic product in 2000 – well before expiration of Hoechst's patent – regardless of the outcome of the patent infringement suit.[49]

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[48] *Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682; *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340 (S.D. Fla. 2000).

[49] *See Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d at 696 & n.7 (the challenged agreement guaranteed Andrx the ability to enter the market with its generic product under a license from Hoechst in January 2000); 698 (license fees and royalties would be refunded if Andrx won the patent infringement suit); 703-04 (agreement provided Andrx a license before

Nor can the holdings of the *Cardizem* and *Terozosin* cases be meaningfully distinguished on the ground that they were not final settlements of litigation. The agreements were couched as interim settlements that disposed of the need to litigate concerning the propriety of injunctive relief while the case was pending. Moreover, agreements in the context of final settlements arguably pose an even greater threat to consumers, because they allow the branded drug maker to avoid a court decision that could invalidate or narrow the scope of its patent.

Finally, Schering also argues that the law at the time of the agreements was "undeveloped." But even if true, that would not affect whether or not liability ought to be assessed on the basis of a *per se* analysis. Respondents' awareness that their conduct was *per se* unlawful may be relevant in deciding on the appropriate remedy, but a *per se* violation in a civil case does not require a knowing and willful violation of law. Schering's quotation from the Statement accompanying the *Abbott/Geneva* consent orders (Schering Brief (US) at 59-60) merely confirms this point. That Statement explained that orders limited to regulating future conduct were appropriate in that matter, but that other remedies, such as disgorgement of illegally obtained profits, would be considered in future cases.[50]

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patent expiration and even if Andrx lost the suit); 705 (same). The patent at issue in *Cardizem* issued in 1995 (*id.* at 686), and did not expire until 2011 (FDA "Orange Book" available at: http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexcl.cfm?Appl_No=020062&Product_No=001&table1=RxFDA (visited Apr. 24, 2002), so the 2000 generic entry date was more than a decade before patent expiration.

[50] Statement of Chairman Robert Pitofsky, et al, *In re Abbott Laboratories*, C-3945 (May 22, 2000), available at http://www.ftc.gov/os/2000/05/abbottgenevastatement.htm.

VI. SCHERING HAD MONOPOLY POWER AT THE TIME OF THE AGREEMENTS WITH UPSHER AND AHP

Respondents' discussion of market definition and monopoly power in their post-trial briefs is based largely on the faulty premise that the only way to prove a monopoly is by defining a relevant market, calculating market shares, and then drawing an inference of monopoly power from those shares.[51] Although this is a common method of proving monopoly power in antitrust cases where direct evidence of anticompetitive effects is not available (such as in merger reviews where one necessarily is predicting an uncertain post-merger future), there is abundant evidence in this case that directly proves that Schering had monopoly power in the market for K-Dur 20 at the time of its agreements with Upsher in 1997 and ESI in 1998. Consequently, the market definition exercise respondents insist upon is unnecessary as a matter of law. Moreover, by applying the market definition methodology to the facts in this case, respondents have fallen prey to the "cellophane fallacy."

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[51] For the purpose of this reply brief, we adopt the convention, frequently employed by economists and some courts, of using the terms monopoly power and market power interchangeably. *See generally* Dennis W. Carlton & Jeffrey M. Perloff, *Modern Industrial Organization* 92 (3d ed. 1999) ("[t]he terms *monopoly power* and *market power* typically are used interchangeably to mean the ability to profitably set price above competitive levels") (emphasis in original). We note, however, that as a matter of law, market power typically is considered less substantial than monopoly power, thus requiring a lower threshold of proof, and that the antitrust violations alleged in the complaint in this case paralleling Sherman Act § 1 theories require only proof of market power or likely anticompetitive effects, not monopoly power. *See, e.g., Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 481 (1992) ("monopoly power under § 2 requires, of course, something greater than market power under § 1."). *But see, e.g., Cost Mgmt. Servs. v. Washington Natural Gas Co.*, 99 F.3d 937, 950 n.15 (9th Cir. 1996) ("The terms 'market power' and 'monopoly power' are used interchangeably herein."); *U.S. Anchor Mfg., Inc. v. Rule Indus.*, 7 F.3d 986, 944 n.12 (11th Cir. 1993) ("The terms 'monopoly power' and 'market power' are synonymous . . . .").

A. Of the Various Methods for Proving Monopoly Power, Direct Evidence Is the Best Evidence

Monopoly power, according to the Supreme Court, "is the power to control prices or to exclude competition." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956) (footnote omitted). This power can be directly established through evidence of competitive harm. "If the plaintiff puts forth evidence of restricted output and supracompetitive prices, that is direct proof of injury to competition which a competitor with market power may inflict, and thus of the actual exercise of market power."[52] As Judge Easterbrook, in an opinion of the Seventh Circuit Court of Appeals, has elaborated: "Market share is just a way of estimating market power, which is the ultimate consideration. When there are better ways to estimate market power, the court should use them."[53] This echoes the Supreme Court's teaching in *FTC v. Indiana Federation of Dentists*, where the Court wrote: "Since the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, proof of actual detrimental effects . . .

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[52] *Rebel Oil Co., Inc. v. Atlantic Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995) (citations omitted). *See also Re/Max Intern., Inc. v. Realty One, Inc.*, 173 F.3d 995, 1016 (6th Cir. 1999) ("There are two ways to establish the first element [of a monopolization charge under Sherman Act § 2], that is, that the defendant holds monopoly power. The first is by presenting direct evidence showing the exercise of actual control over prices or the actual exclusion of competitors. The second is by presenting circumstantial evidence of monopoly power by showing a high market share within a defined market.") (citations and internal quotation marks omitted).

[53] *Ball Memorial Hospital, Inc. v. Mutual Hospital Insurance, Inc.*, 784 F.2d 1325, 1336 (7th Cir. 1986) (citation omitted). *See also Flegel v. Christian Hosp.*, 4 F.3d 682, 690 (8th Cir. 1993) ("Market power is . . . simply a surrogate for actual anticompetitive effects . . . ."); *Oltz v. St. Peter's Community Hosp.*, 861 F.2d 1440, 1448 (9th Cir. 1988) ("Defining the market is not the aim of antitrust law; it merely aids the search for competitive injury.").

can obviate the need for an inquiry into market power, which is but a surrogate for detrimental effects."[54]

By arguing that anticompetitive effects in a market cannot be shown unless complaint counsel first shows that Schering had a large share of some market, respondents make exactly the same mistake as made by the respondent in *Toys "R" Us, Inc. v. FTC*.

> [Toys "R" Us] seems to think that anticompetitive effects in a market cannot be shown unless the plaintiff, or here 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. The other, more conventional way, is by proving relevant product and geographic markets and by showing that the defendant's share exceeds whatever threshold is important for the practice in the case.

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

Schering and Upsher also have it backwards. They don't want to acknowledge that market definition is only a means to an end, that end being assessing whether the conduct at issue has actual or potential anticompetitive effects.[55] And, they don't want to acknowledge that proof of actual detrimental effects obviates the need for the market definition exercise they propose.

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[54] 476 U.S. 447, 460-61 (1986) (citation and internal quotation marks omitted). *See also Re/Max*, 173 F.3d at 1019 (applying the *IFD* standard to a monopolization claim under Section 2 of the Sherman Act); *Great Western Directories, Inc. v. Southwestern Bell Tel. Co.*, 63 F.3d 1378, 1384 (5th Cir. 1995) (same).

[55] *See, e.g., In re Coca-Cola Bottling Co.*, 118 F.T.C. 452, 540 (1994) ("The purpose of defining a relevant market is to identify a market in which market power might be exercised and competition thereby diminished.") (citations omitted).

The ultimate goal of any antitrust analysis is to determine whether the specific business practice at issue – be it a merger, single-firm conduct that may affect competitors, or an agreement among competitors (as here) – has actual or potential anticompetitive effects. As Justice Breyer put it in *California Dental Association*, the purpose of the inquiry is to determine whether there is reason to believe that the conduct at issue makes "a real world difference" to consumers. 526 U.S. 756, 793 (1999) (Breyer, J., dissenting). These effects may include any effect on price, output, quality, service, choice, convenience, innovation, or anything else valued by consumers, that deviates from the competitive level.

In this case, direct evidence of anticompetitive effects clearly demonstrates that Schering had monopoly power in the market for K-Dur 20 at the time it entered into its agreements with Upsher and AHP. This evidence obviates the need, as a matter of law, to undertake the market definition exercise respondents advance, with their misplaced reliance on *Brown Shoe Co. v. United States.*[56]

B. There Is Abundant Direct Evidence of Schering's Monopoly Power

As set forth in detail in complaint counsel's post-trial brief, there is abundant direct evidence in this case demonstrating that: (1) Schering enjoyed substantial pricing power over K-Dur 20 prior to generic entry; (2) Schering had monopoly power in the market for K-Dur 20; and

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[56] 370 U.S. 294 (1962). Sole or primary reliance on *Brown Shoe* in defining antitrust markets, as respondents appear to advocate, has come under considerable scholarly criticism. *See, e.g.*, Carlton & Perloff at 614 ("The application of [*Brown Shoe's*] laundry list of criteria has not led to precision in defining a market for antitrust purposes.") (footnote omitted).

(3) Schering's agreements with Upsher and AHP to delay generic entry were likely to have, and did in fact have, actual detrimental effects on consumers.[57]

Schering's monopoly power is directly proven by evidence that:

1. In the years prior to generic K-Dur 20's entry, sales of K-Dur 20 continued to grow compared to the sales of lower-priced potassium chloride supplements, even in the face of Schering's yearly relative price increases for K-Dur 20 (CPF 972-87);

2. Schering, Upsher, and • • • • all forecast that generic K-Dur 20's entry would quickly take a large share of branded K-Dur 20's sales and would significantly lower the average market price paid for K-Dur 20 and its generics (CPF 83 (in camera), 84, 96-97, 816-20 (in camera), 956-57, 962, 964-67, 970);

3. Schering, in its plans to introduce its own generic K-Dur 20, recognized that it could profitably sell its generic product at substantially lower prices – 50 percent lower – than its identical branded K-Dur 20 product (CPF 1115); and

4. Upsher's 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 when it finally entered the market in September 2001 (CPF 988-92).

Moreover, the conclusion that Schering had monopoly power is consistent with the large body of empirical research on pharmaceutical competition that shows the significant impact that generics have on their branded counterparts' sales and on the average price paid for such drugs.[58]

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[57] Schering, when it first developed K-Dur 20, acquired its monopoly legally and was entitled to charge a monopoly price for its product. *See, e.g., Blue Cross & Blue Shield United of Wisc. v. Marshfield Clinic,* 65 F.3d 1406, 1415 (7th Cir. 1995) (Posner, J.) ("a lawful monopolist can charge what it wants"). Our case does not challenge this. Instead, we challenge the illegal maintenance of this monopoly through exclusionary conduct, the effect of which was to delay competition to K-Dur 20 and consequently to delay the price of 20 mEq, microencapsulated, potassium chloride supplements from falling to a more competitive level.

[58] *See, e.g.*, Richard E. Caves, Michael D. Whinston, & Mark A. Hurwitz, *Patent Expiration, Entry and Competition in the U.S. Pharmaceutical Industry*, in Brookings Papers on Economic Activity: Microeconomics 1 (1991); Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (1998); Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of*

Taken together this evidence conclusively establishes that Schering had monopoly power – "the power to control prices" – in the market for K-Dur 20 at the time it entered into the agreements with Upsher and AHP. This evidence also proves that Upsher's and AHP's agreements with Schering, by delaying generic entry, made a "real world difference" to consumers and to competition at the time they were entered in 1997 and 1998. This direct evidence of anticompetitive effects obviates the need to engage in the static market definition exercise that Schering and Upsher advocate in their post-trial briefs.

C. Reliance on Other Methods Establishing Monopoly Power Is Unnecessary

Upsher, in its post-trial brief, provides a two-page 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 to help establish monopoly power. Upsher Brief at 107-08. Because Professor Bresnahan did not perform the specific tests Upsher identifies, Upsher asks this Court to infer that complaint counsel did not prove anticompetitive effects from the respondents' agreements. *See* Upsher Brief at 106.

Professor Bresnahan knows these methodologies well, and he has used them in the past when he was the chief economist at the Department of Justice Antitrust Division and as an academician. In fact, Professor Bresnahan is one of the pioneers in developing methodologies

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Pharmaceuticals, 6 J. Econ. & Mgmt. Strategy 75 (Spring 1997); Henry G. Grabowski and John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J. L. & Econ. 331 (Oct. 1992); Roy Levy, *Federal Trade Commission, The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change*, Bureau of Economics Staff Report (1999); Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards* (1993).

for measuring market power.[59] But, as he testified at trial, the choice of method is a function of "the available body of facts and information." Tr. 6:1224 (Bresnahan). Here the direct evidence of anticompetitive effects is so strong that it was not necessary to perform any of these other methodologies. As Professor Bresnahan explained it:

> Economists define markets in order to establish the area within which competition will decrease prices. A market is an area within which an addition of competition will lower prices or a subtraction of competition, a lessening of competition, will raise prices. . . .
> . . .
>
> Using that principle . . . I defined the market to be . . . K-Dur 20 and generics for it because it was clear that the competition within that class would lower prices, that the removal of competition within that class of products would raise prices, and in neither case trivial. It would raise them and lower them substantially.

Tr. 6:1222-23 (Bresnahan).

D. Respondents Misconstrue "Reasonable Interchangeability"

At the heart of the respondents' product market discussion is the argument that many other potassium chloride supplements are "reasonably interchangeable" with K-Dur 20. While there is no doubt that numerous pharmaceutical products in addition to K-Dur 20 contain potassium chloride and can be used to treat potassium deficiency ("hypokalemia"), this provides no proof that those other therapeutic agents are "reasonable" substitutes for K-Dur 20 in the antitrust sense. First, as the Supreme Court explained in *Brown Shoe*, the reasonable interchangeability of use between products provides only "[t]he outer boundaries of a product

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

market . . . within this broad market, well-defined submarkets may exist which, in themselves, constitute product markets for antitrust purposes."[60] Second, as the Supreme Court teaches in *du Pont*, reasonable interchangeability is not just a question of the functional substitutability of products, as respondents suggest, but rather must take into account "price, use, and qualities." 351 U.S. at 404.

K-Dur 20, as discussed in detail in our post-trial brief and findings, has a number of important characteristics that distinguish it from the other potassium chloride products that were available at the time of its introduction. CPF 1037-70. This helps explain why it was priced significantly higher than most other products, and nonetheless continued to grow its sales despite significant yearly price increases relative to the other products. CPF 972-87. This also explains why Upsher and AHP were so eager to get into the business of selling their own 20 mEq potassium products. For if all potassium chloride products are fungible (as respondents suggest), why bother?[61] Dr. Kerr, Upsher's economic expert, knows why, as he acknowledged at trial: "If a pioneer's patent did not provide any market power, there would be no reason for a generic to challenge the patent." Tr. 27:6571 (Kerr). More importantly, one of complaint counsel's health plan witnesses, Russell Teagarden, who is also a pharmacist, explained why there are so many different potassium chloride supplements and why health plans keep a number of them on their formularies. As Mr. Teagarden explained, this is the case not because all potassium chloride products are freely substitutable, but rather the opposite, they are not freely substitutable.

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[60] 370 U.S. at 325 (citing *du Pont*).

[61] Curiously, at one point in its post-trial brief, Upsher actually argues that K-Dur 20 had some "inherent disadvantage" compared to other potassium chloride products because of its large dosage size that made it difficult for patients to swallow. Upsher Brief at 78-79.

> The reason is that potassium chloride is not well tolerated by patients. It's not pleasant – by itself in solution, it's not a pleasant taste, and it can be sufficiently unpleasant and poorly tolerated that people won't take it. So, over the years, the decades, there have been a variety of dosage forms that have been engineered to make it more palatable, acceptable, better tolerated, and patients tend to do better with one or the other, and this happens to be the range that is necessary to find one for a patient to accept.

Tr. 2:207-08 (Teagarden).

The case law recognizes that when products, like pharmaceuticals, can be used for similar purposes but differ in terms of price, quality, consumer preferences, or other significant attributes, the products are considered to be differentiated. And, although differentiated products "compete" along some dimensions, as the Third Circuit Court of Appeals ruled in *Smith-Kline Corp. v. Eli Lilly & Co.*, a case involving the pharmaceutical industry, a relevant antitrust market should include only those products that "have the ability – actual or potential – to take significant amounts of business away from each other." 575 F.2d 1056, 1063 (3d Cir. 1978). A bioequivalent generic version of a branded drug can take significant amounts of business away from its branded counterpart, precisely because they are freely substitutable. Non-AB rated drugs cannot.[62]

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[62] *See, e.g., In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 297, 310-11 (E.D. Mich. 2001) ("AB-rated generics are freely substitutable and interchangeable with their brand name counterparts. Industry experts describe them as perfect substitutes for the brand name drug . . . In the pharmaceutical industry, there is a government-assured complete interchangeability of drug products. This is why pharmacies are allowed to substitute the lower-priced generic versions of brand name drug products that have been demonstrated to the FDA to be therapeutically equivalent.")

E. Respondents Fall Prey to the "Cellophane Fallacy"

Application of the market definition methodology respondents advance to the facts in this case produces an erroneous result commonly known as the "cellophane fallacy." The cellophane fallacy is derived from the Supreme Court's decision in *du Pont*, which questioned whether du Pont had a monopoly in the market for cellophane. Critics of the decision have recognized that in cases where a monopolist already is exercising its monopoly power, using the market definition methodology (and identifying substitutes and trying to estimate the "cross-elasticity" of demand between apparent substitutes)[63] is likely to lead to an erroneous conclusion about monopoly power. This is because a rational, profit-maximizing monopolist will raise its prices up to the monopoly level, which also is the point at which some customers will substitute away from the monopoly-priced product to less desirable alternatives, even though they would not have substituted to these products if their preferred product were priced at a competitive level. As Judge Learned Hand recognized, "substitutes are available for almost all commodities, and to raise the price enough is to evoke them."[64] Because even the products of a monopolist have substitutes, the fact of substitution, as Professor Bresnahan pointed out, provides "no information . . . to discriminate between the hypotheses of competition and monopoly." Tr. 34:8011 (Bresnahan). *See also* CPF 1086-89.

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[63] Cross-elasticity of demand is "the percentage change in quantity demanded in response to a 1 percent change in another product's price." Carlton & Perloff at 736.

[64] *United States v. Aluminum Co. of Am.*, 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").

The consequence of using the market definition methodology and identifying substitutes to infer monopoly power where a monopolist already exercises its power is to conclude that a relevant market is much larger than it actually is – because inefficient substitution by customers is mistaken for competition. This leads to the erroneous conclusion that a firm is not a monopolist because its monopoly-priced product "competes" with other products, and that its market share is too small to infer a monopoly.[65]

Much of the testimony of Schering's economic expert, Dr. Addanki, concerning whether other potassium chloride products are a constraint on K-Dur 20's pricing is subject to the cellophane fallacy. CPF 1082, 1086-89.

In addition to falling prey to the cellophane fallacy, Dr. Addanki and Upsher make a number of other basic economics mistakes. First, Upsher argues that Dr. Addanki studied the pricing of K-Dur 20 and a number of other potassium chloride supplements and found that one or more of the other products were priced similarly to, or even above, that of K-Dur 20. Upsher Brief at 82. By itself, this proves nothing. To try to draw any meaningful conclusion from such evidence one must also look at whether these products were quantitatively important in terms of the number of units sold. CPF 1108. Second, Upsher then turns around and argues that record evidence shows that the 30 percent price difference between K-Dur 20 and generics was causing the sales of generics to rise. Upsher Brief at 85. This argument not only illustrates the cellophane fallacy (at a high enough price everything has substitutes) and ignores the fact that K-Dur 20's sales were increasing even as its price rose, but it also implicitly exhibits another basic

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[65] *Cf.* Carlton & Perloff at 614 (discussing the cellophane fallacy and the difficulties that may arise in trying to define markets where a company is already a monopolist).

economic fallacy on Upsher's part: the notion that a firm with monopoly power can charge any price it wants because it is not constrained by anything.

Third, Upsher argues that Dr. Addanki's testimony about Schering's "relatively large marketing and advertising expenditures" shows that there was a lot of competition. Upsher Brief at 83, 87. The fact that Schering advertised K-Dur 20 tells us almost nothing about Schering's monopoly power, for even a monopolist wants to increase the demand for its product in order to increase its sales. Tr. 6:1229-30 (Bresnahan). *See also* CPF 1124. Lastly, Upsher argues that Schering "spent" millions in rebates to its K-Dur 20 customers and that these "investments . . . would not have been made by a monopolist insulated from competition." Upsher Brief at 87. Here too Upsher has 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 is able to price discriminate among its customers. *See, e.g., In re Brand Name Prescription Drugs Antitrust Litigation*, 186 F.3d 781, 783 (7th Cir. 1999) (Posner, J.) ("[p]rice discrimination implies market power"). CPF 1092-93.

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

Respondents made much at trial and in their post-trial briefs about the possibility of substituting two 10 mEq potassium chloride supplements for one K-Dur 20. Apparently, Upsher had a program that sought to promote this concept prior to the eventual launch of its generic 20 mEq product. This program, however, was not successful (CPF 1024-26), except for a period of time when there was a shortage of K-Dur 20. From this, respondents would like this Court to draw the inference that 10 mEq products are reasonable substitutes for K-Dur 20. Rather than

proving actual competition, however, this evidence illustrates how respondents have fallen prey to the cellophane fallacy. It also demonstrates that 10 mEq products do not constrain the pricing or sales of K-Dur 20 in any meaningful way.

Obviously, when demand for a product is greater than its supply, people search for alternatives. So, it is no surprise that some people might have substituted two 10 mEq potassium supplements in place of one K-Dur 20 when there was a shortage of K-Dur 20. Similarly, if there were a shortage of cars (as, say, in China), more people would take public transportation or ride bicycles to work. But this is a far cry from saying that the antitrust laws would (or should) permit General Motors, Ford, and Daimler-Chrysler to jointly set their automobile prices or output, just because substitute modes of transportation are available. It also doesn't prove that bikes and busses constrain the pricing of cars in any meaningful way. When there was a shortage of K-Dur 20, people needing potassium supplements sought out second-best alternatives; when there was a sufficient supply of K-Dur 20 to meet demand, people paid the higher monopoly price to get the preferred product.

G. The Agreements between Schering, Upsher, and AHP Excluded Competition

Both Schering and Upsher proclaim that their agreement got a low-priced generic to market sooner than might have occurred by continuing the litigation of the patent infringement suit. Schering, for example, asserts, in its post-trial brief, that "[c]onsumers are enjoying the benefits of low-priced generic K-Dur 20 today because of the settlement." Schering Brief (US) at 74. Similarly, Upsher's counsel, Mr. Curran, during his opening statement 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 . . . ."[66] Tr. 1:74-75. In its post-trial brief Upsher goes on to argue: "Upsher-Smith's June 1997 had the effect of opening the potassium market up to three generic versions of K-Dur 20. Bringing more products to the market was a procompetitive effect of the Agreement." Upsher Brief at 57 (internal citations omitted). If earlier generic entry is good for consumers and is procompetitive (which it is), then the reciprocal must be true as well: delayed entry harms consumers and is anticompetitive. And, if delaying generic K-Dur 20's entry harms consumers and competition, then Schering must be exercising market power.

It is clear that by delaying the entry of generic K-Dur 20, the agreements between Schering and Upsher and Schering and AHP excluded competition. Thus, the second standard for proving monopoly power as articulated by the Supreme Court in *du Pont* "the power . . . to exclude competition" – is also met in this case. *du Pont*, 351 U.S. at 391. This further proves that Schering had monopoly power, and that it sought to protect this power, when it entered the agreements with Upsher and AHP.[67]

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

Contrary to Schering's and Upsher's insinuations at trial and in their post-trial briefs, a single brand or product can constitute a relevant product market for antitrust purposes. Indeed,

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[66] Curiously, Dr. Addanki, whom respondents relied upon to testify about product market issues at trial, opined that generic entry actually may harm consumers. CPF 1144-49.

[67] *See also* 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). *Cf.* Robert H. Bork, *The Antitrust Paradox: A Policy at War with Itself* 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.").

the Supreme Court expressly has found that "in some instances one brand of a product can constitute a separate market." *Kodak*, 504 U.S. 482 (citations omitted). And, as Judge Posner observed in *Brand Name Prescription Drugs*, "[i]t would not be surprising . . . if *every* manufacturer of brand name prescription drugs has some market power." 186 F.3d at 787 (emphasis in original). 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 had, including its ease of dosing and microencapsulation. CPF 1037-70. In fact these differences were sufficiently significant that during his opening Mr. Nields sought to demonstrate how unique K-Dur 20 was by dropping a tablet in a glass of water, while heralding Schering as "the only one" to figure out how to make 20 mEq dosages. Tr. 1:51. Now respondents wish to imply that all potassium chloride products are fungible. The commercial realities, however, show that no other potassium chloride product could have the effect on K-Dur 20's sales and profitability that entry of a generic version of K-Dur 20 was expected to have and, in fact, did have. Accordingly, the relevant market in which to analyze the anticompetitive effects of Schering's agreements with Upsher and AHP is the sale of K-Dur 20 and its generic equivalents in the United States.

This market accurately reflects the unique competitive dynamic that typically exists between a branded drug and its generic counterpart.[68] Indeed, it is precisely this unique

[68] Schering's counsel, Mr. Nields, understands the commercial realities of competition between a branded drug and its generic equivalent, as revealed by the following questions he asked during the cross-examination of Professor Bresnahan:

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.

Schering and Upsher, nonetheless, insist the relevant market consists of all potassium chloride supplements, and that K-Dur 20's share of that market is too small to infer monopoly power.[69] To accept respondents' definition of the relevant market as including all potassium supplements, one would have to ignore commercial realities and conclude that the entry of generic K-Dur 20 made little difference to consumers and to competition. Indeed, to accept respondents' arguments about the absence of monopoly power one would have to conclude that Schering was acting irrationally when it spent millions of dollars bringing its patent lawsuits against Upsher and AHP to prevent them from entering this allegedly "crowded" market. Upsher Brief at 1. One would also have to conclude that Upsher and AHP were acting irrationally when

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Q: Now, Professor, isn't it true that the competition that exists between a brand name company and it's A-B rated generic has some very special features to it?
A: Yes. I mean, the – you mean, the competition between the brand name firm's product and the A-B rated generic to the product.
Q: Yes, I should have asked the question that way.
A: Yes.
. . .
Q: And isn't it true that the generic virtually always, if not always, underprices the brand name?
A: That's true, too.
. . .
Q: And they always take sales away from the brand name, correct?
A: Yes.

Tr. 6:1176-80 (Bresnahan).

[69] *See, e.g.*, Upsher-Smith's Memorandum of Law in Support of Its Motion to Dismiss at 18-23 (Feb. 12, 2002).

they made their investments, including the costs of defending against Schering's lawsuits, to develop and market generic K-Dur 20, especially since Upsher and AHP already marketed a number of other allegedly "competing" non-20 mEq potassium chloride products.

Record evidence of the commercial realities belies respondents' contentions. 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 by delaying the entry of generic K-Dur 20 in accordance with their illegal agreements, Schering, Upsher, and AHP harmed competition and consumers.

There is no need to infer anticompetitive effects from circumstantial evidence about market share in this case. The real world anticompetitive effects of the illegal agreements – and hence Schering's monopoly power – are directly proven.[70]

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[70] Upsher argues that complaint counsel have failed to establish that it had the specific intent to enter into a conspiracy to monopolize. Upsher Brief at 120-24. The cases it cites in support of its argument, however, do not contradict the law or evidence set forth in our post-trial brief. *See* Complaint Counsel Brief at 98-101. Many of the cases Upsher cites involve defendants in vertical relationships (e.g., a supplier and its customers), where a shared monopolistic intent makes no sense, as contrasted with the horizontal relationship between direct competitors as in this case, where a conspiracy to monopolize does make sense. *See Belfiore v. New York Times Co.*, 826 F.2d 177, 183 (2d Cir. 1987) (finding no specific intent where vertical relationship "*created* competition"); *In re Microsoft Corp. Antitrust Litig.*, 127 F. Supp 2d 728, 731-32 (D. Md. 2001) (holding no specific intent where vertical relationship gave co-conspirators divergent incentives); *Genetic Sys. Corp. v. Abbott Labs.*, 691 F. Supp. 407, 422 (D.D.C. 1988) (same). The other cases Upsher string cites stand for the rather obvious proposition that a plaintiff must demonstrate that the defendants agreed to accomplish something the antitrust laws prohibit. *See International Distrib. Ctrs. v. Walsh Trucking Co., Inc.*, 812 F.2d 786, 795 (2d Cir. 1987) (holding no specific intent where plaintiff failed to "offer a scintilla of evidence that" the defendants agreed to do anything that would assist the alleged price-fixing conspiracy); *Building Indus. Fund v. Local Union No. 3*, 992 F. Supp. 162, 186 (E.D.N.Y. 1996)

VII. SCHERING AND UPSHER ENTERED INTO THEIR AGREEMENT KNOWING THAT IT WOULD ENSURE THAT UPSHER DID NOT TRIGGER THE HATCH-WAXMAN EXCLUSIVITY PERIOD UNTIL 2001

Respondents' briefs suggest that Upsher's entitlement to the Hatch-Waxman 180-day exclusivity period is relevant to this case only if they entered into their agreement with the specific intent to manipulate the exclusivity period. Indeed, Upsher once again attempts to import criminal intent standards into this case.[71] In fact, however, the 180-day exclusivity period is relevant to the Schering/Upsher Smith agreement in two respects, neither of which requires any showing of specific intent.

First, the 180-day exclusivity period provided an additional reason for Schering to pay Upsher to stay off the market. Schering knew that Upsher was the first to file an ANDA with a Paragraph IV certification, and thus was eligible for the exclusivity period. CX 225 at SP 08 00008. Moreover, although Upsher's brief states that "the 180-day period was never discussed during negotiations," Upsher's President, Ian Troup, had in fact referred to that very issue, stating to Schering executive Martin Driscoll that Upsher's launch of its generic K-Dur 20 product could

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(holding no specific intent where the plaintiff failed to offer any evidence of agreement to any act or group of acts that would violate the Sherman Act). The first group of cases are of no relevance because Schering and Upsher were horizontal competitors with strong incentives to monopolize the K-Dur 20 market at the time of the agreement. The second set of cases are inapposite because the settlement agreement itself provides direct evidence of respondents' shared intent to allow Schering to maintain its monopoly (and their intent to share the monopoly profits) until September 1, 2001.

[71] *See* Upsher Brief at 118, *citing United States v. Critzer*, 498 F.2d 1160 (4th Cir. 1974) (criminal tax evasion); *James v. United States*, 366 U.S. 213 (1961). Upsher also cites *AFL-CIO v. Fed. Election Comm'n*, 628 F.2d 97, 100 (D.C. Cir. 1980) (civil penalty provision requiring "knowing and willful" violation of election laws).

"open a floodgate" of generic competition to K-Dur 20. CX 1529 (Troup III) at 88:5-23.[72] Although much attention has been given to the uncertainty regarding the effect of settlement on Upsher's eligibility for the exclusivity period that existed at the time of their June 1997 agreement, one thing was absolutely clear: Without a settlement, an Upsher launch of its product would undoubtedly "open the floodgate" to other firms seeking to offer generic competition to K-Dur 20. In contrast to that certain outcome, by paying Upsher to forestall entry, Schering had a reasonable possibility of delaying the opening of the gate. It is wholly implausible that Upsher and Schering acted unaware of that possibility.

The second way in which the 180-day exclusivity period is relevant concerns the ultimate effect of Schering's agreement with Upsher. Upsher did in fact retain its exclusivity rights after the settlement. CX 612 at AHP 13 00067 (FDA letter to AHP advising that final approval of its product was stayed pending expiration of 180-day exclusivity period). As a result, Schering's agreement with Upsher-Smith not only delayed entry by Upsher, but also had additional anticompetitive effects – because any delay in Upsher's market entry would also serve to avoid Upsher's triggering of its Hatch-Waxman exclusivity rights. The complaint does not charge that this additional effect created a separate and independent violation of law, or allege a separate conspiracy concerning the exclusivity period.[73] Rather, the impact on third parties is merely

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[72] Mr. Troup testified that the "open the floodgate" threat occurred in a telephone conversation with Mr. Driscoll. *See* CX 1529 (Troup III) at 87-88. At trial, Mr. Troup carefully stated that the subject of 180-day exclusivity "was never raised at any time by any person on either side of the negotiating table *at any meeting* at all." Tr. 23:5492-93 (Troup) (emphasis supplied).

[73] Schering's brief acknowledges that no independent violation relating to the 180-day exclusivity period is at issue in the case (*see* Schering Brief (US) at 75 n. 23), but continues to quote a portion of a speech by Commissioner Leary (*id.* at 76) that expressly refers to issues

another effect of the unlawful agreement to exchange payments for delayed generic entry. This additional effect on third parties arises from, and is directly attributable to, the effect of the payments on entry by Upsher.[74] And the effect arises notwithstanding the uncertainty that it would occur at the time the parties entered into the agreement.

As the cases cited by Upsher suggest, the parties' uncertainty that their agreement would maintain an obstacle to generic entry *would* be relevant in an action that sought to impose criminal or civil penalties on respondents. The remedy sought here, however, involves no punishment and requires no finding of a knowing or intentional violation of law. Respondents' specific intent argument appears to rest exclusively on language in Your Honor's October 31, 2001 Order denying their motions to dismiss the complaint, but we believe their reading of the order is incorrect. The order emphasizes the element of concerted, rather than unilateral, action charged in the complaint.[75] It is entirely consistent with the decision in the *Cardizem CD* case,

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regarding agreements not to waive exclusivity *in the absence of a "reverse" payment.* Thomas B. Leary, Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part II (May 17, 2001) available at http://www.ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm ("Absent reverse payments, the competitive impact [of agreements not to waive exclusivity] is ambiguous").

[74] Upsher argues that had it not settled it might have: (1) lost the patent case, and (2) still retained its exclusivity rights, with the result that other generics would have been blocked until 180 days after patent expiration. As we noted above, the view that Upsher would have retained its exclusivity rights after losing the patent case has no support in FDA or court pronouncements, and there was conflicting expert testimony in this proceeding on whether that is currently the law. But in any event, complaint counsel's expert, Mr. Hoffman, made it clear that his opinion that a losing first ANDA filer would retain exclusivity is based on his view of the law as it stands today, and not at the time of Upsher's June 1997 agreement with Schering. See CPRF (Schering) 1.482.

[75] *See Order Denying Motions of Respondents Schering-Plough and Upsher-Smith to Dismiss the Complaint* (October 31, 2001) at 9 (noting that complaint sufficiently alleged concerted action, but that respondents could seek to prove at trial that the exclusionary effect was

where the court distinguished between effects arising from a generic firm's unilateral decision not to trigger its exclusivity period, and concerted action that has that effect.[76]

Finally, respondents' "no harm-no foul" argument – suggesting that delaying the triggering of Upsher's exclusivity period did not actually serve to block any firm that was otherwise in a position to go to market – is plainly incorrect. By delaying Upsher's entry, the parties' agreement would delay the elimination of a barrier to generic entry. The fact that outside events created additional obstacles to their entry – in AHP's case, its agreement with Schering, and in Andrx's case, its lack of tentative FDA approval – does not undermine the clear anticompetitive tendency of the agreement.[77]

VIII. THE COLLATERAL RESTRAINTS ARE FURTHER EVIDENCE OF THE ANTICOMPETITIVE CHARACTER OF THE AGREEMENTS

Both respondents argue that the agreements' ban on competing with *any* 20 mEq micro-encapsulated potassium chloride product is merely a reasonable adjunct to a legitimate patent settlement.[78] But whatever the justification might be in settlements that do not involve a payment for delay, the provisions in these agreements were not ancillary to a legitimate settlement. Here, the requirements served to further anticompetitive arrangements designed to keep Upsher and

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a consequence of the operation of federal law and unilateral action by Upsher).

[76] *See Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d at 658 (Hatch-Waxman Amendments permit certain unilateral action but do not authorize agreements to restrain trade).

[77] *See Andrx Pharm., Inc. v. Biovail Corp.*, 256 F.3d 799, 806-808 (D.C. Cir. 2001) (absence of tentative FDA approval did not preclude injury to later ANDA filer allegedly blocked by agreement between branded drug company and first ANDA filer).

[78] *See* Schering Brief (ESI) at 32 n.25; Upsher Brief at 111-14.

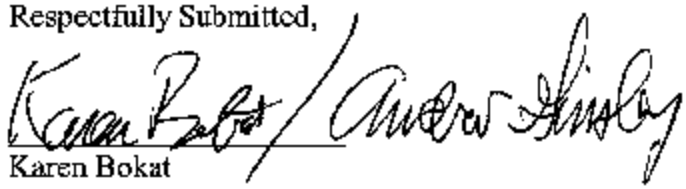
AHP from undertaking any generic competition to K-Dur 20 for several years. This was part of the package of restraints that Schering bought with its multi-million dollar payments.

Moreover, Schering makes no mention whatsoever of the other restraints included in its agreement with AHP: the bars on conducting bioequivalence studies, selling more than one generic product between 2004 and 2006, and AHP's transferring its ANDA. Indeed, if AHP's position in the infringement case was as weak as Schering would have us believe, then AHP might logically seek to undertake further research to design around the '743 patent. The more extensive restraints Schering imposed on AHP are unlawful and are further evidence that the agreement was designed to delay generic entry.

CONCLUSION

For the reasons set forth above and in our post-trial brief and findings, respondents' acts and practices constitute unfair methods of competition in violation of Section 5 of the FTC. Accordingly, we respectfully request that Your Honor issue the proposed order appended to our post-trial brief.

Respectfully Submitted,



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APPENDIX

COMPLAINT COUNSEL'S REPLY TO SCHERING'S DISCUSSION OF THE MERITS OF THE UNDERLYING PATENT LITIGATIONS

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I. THE OUTCOME OF SETTLED PATENT LITIGATION CANNOT BE RELIABLY PREDICTED

Schering admits, at least with regard to the Upsher case, that it is impossible to say who would have won the settled patent litigation, making any competition that might have resulted from continuation of the litigation "unknown and uncertain."[1] Schering's own expert, Mr. O'Shaughnessy, a patent trial lawyer, testified that litigants seek settlement because patent litigation is by its very nature unpredictable.[2] In obvious contradiction, however, Schering asks this court to predict that it would have won its patent litigations against AHP[3] and Upsher.[4] Recognizing the inconsistency of its own theories, Schering also provides an alternative theory that requires this court to determine that the split of the patent life in the two agreements "fairly

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[1] Schering Brief (US) at 63, 74.

[2] Tr. 29:7065 (O'Shaughnessy).

[3] Schering Brief (ESI) at 33.

[4] Schering Brief (US), Attachment A at 11.

reflects the relative strengths of the parties' positions on the merits as set forth in and supported by the record before the district court."[5]

The court should decline Schering's suggestion that it take on either task. As explained in complaint counsel's Post-Trial Brief, such a determination is irrelevant to the antitrust analysis of the settlement agreements. Furthermore, it is not possible to reliably predict the outcome of patent litigation that settled or to reliably and precisely predict the probability that one side or the other would have won. Schering's theory that the split in the patent life reflects the probability of the outcome of the litigation requires that that probability be determined with an unattainable degree of precision and accuracy in order to provide any meaningful comparison. Even if it were possible to assess the probabilities within a 10% range - and it is not - the comparison Schering suggests would miss agreements that cost consumers tens, even hundreds of millions of dollars.[6]

There are myriad reasons that we cannot predict the outcome. We cannot recreate the conditions of the underlying patent litigations. The defendants in those lawsuits, Upsher and AHP, no longer have any incentive to defend their products against allegations of infringement. We can never know how the parties would have developed the evidence and legal arguments, what evidence would have been admitted at trial, or how those courts would have weighed the evidence,[7] assessed witness credibility and viewed the legal issues.[8] As Schering's expert, Mr.

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[5] Schering Brief (US), Attachment A at 11; Schering Brief (ESI), Attachment A at 12.

[6] *See* Complaint Counsel's Post-Trial Brief at 73-74 for an explanation of the degree of precision required for Schering's proposed analysis.

[7] The only available evidence on the district court judges' views of the merits is the transcripts of the hearings in the underlying litigations. Schering ignores these transcripts in arguing the likely outcome of the litigations. *See* SPX 1305* (Transcript of Hearing on Upsher's Motion for Summary Judgment); •

O'Shaughnessy, explained, even parties in patent litigation cannot reliably predict the outcome, particularly because they cannot anticipate how the evidence or arguments will be perceived by the fact finder.[9] Schering further admits, through both its attorney and its patent experts, Mr. O'Shaughnessy and Mr. Miller, that the probabilities of either side winning cannot be precisely measured.[10]

Schering relies on the opinion testimony of a patent attorney, Mr. Miller, to support its assertions regarding the two underlying patent litigations. Mr. Miller's opinion is merely his personal and subjective view of the limited record he had available to him. He had no access to information relevant to the merits that the parties withheld as privileged and he did not review the complete record. His views were not based on the parties' own contemporaneous assessments of the litigations.[11] He admittedly could not know how the court in the underlying litigation would have viewed the evidence and arguments of the litigants, or even what that evidence and arguments would be.[12] He had no knowledge of the judges' impressions of the merits of the

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• • • The most telling fact about this evidence may be that Schering settled • • • • • immediately following the hearings. CPF 111, 828-831.

[8] *See* Tr. 15:3288-95 (Miller); •; CPF 1360-63.

[9] Tr. 29:7116-17 (O'Shaughnessy).

[10] Tr. 13:775 (Nields) ([W]e don't purport to try to be mathematical about it.); Tr: at 29:7119 (O'Shaughnessy) (A prediction can only be a "rough approximation."); CPF 1356-1358.

[11] Tr. 15:3289-90 (Miller).

[12] Tr. 15:3288-92 (Miller); •

litigations.[13] Thus, he had no basis for predicting how the courts in the underlying patent litigations would have decided those cases.

To the extent that Mr. Miller attempts to predict the probable outcome of the litigations, or that Schering attempts to use his opinion to support such a prediction, Schering simply proffers unreliable speculation. Although complaint counsel does not renew its motion to exclude Mr. Miller's testimony from evidence, the framework for analyzing reliability provided by the Supreme Court in *Daubert* is instructive in assessing whether Mr. Miller's opinion testimony constitutes reliable evidence and the weight it should be accorded. The Supreme Court, in *Daubert*, proved four guides as to whether a theory or technique is reliable: (1) whether the theory or technique can be tested; (2) whether the theory or technique is subject to peer review; (3) the existence or maintenance of standards controlling the technique's operation; and (4) whether the theory or technique has achieved general acceptance.[14] Testimony predicting how a court would have decided settled patent litigation, or even the probability that one side would have won, fails on every test. As Mr. Miller conceded, such testimony can never be tested. He knows of no instance in which a court has accepted such testimony as reliable.[15] Schering has pointed to no known or generally accepted technique of handicapping settled patent litigation, no method of peer review and no applicable standards. Mr. Miller's testimony is not a reliable indicator of the likely outcome of the settled cases.

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[13] Tr. 15:3290-91 (Miller).

[14] *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593-95 (1995).

[15] Tr. 15:3295-96 (Miller).

Schering attempts to mask the unprecedented nature of the determination on likely outcome that it requests from this court by analogizing it to the determinations that courts make when deciding preliminary injunction motions or reviewing class action settlements.[16] The analogy fails in both instances. When a federal district court judge evaluates a patentee's likelihood of success on the merits in the course of deciding a motion seeking a preliminary injunction, or reviews a proposed class-action settlement, he has before him the plaintiff and the defendant, the parties with the best command of the evidence and the incentive to champion their respective positions. In a hearing on a preliminary injunction, the judge's task is to assess the likelihood of success in that litigation, before that very same judge, based on a presentation by the same parties, with some of the same witnesses and evidence he would expect to see at any eventual trial. That is a far cry from what Schering asks this court to do: assess the likely outcome of litigation that settled five years ago, before a different judge, involving different parties, different witnesses and different evidence.

When reviewing a class action settlement, the trial judge evaluates whether the settlement is fair, adequate and reasonable. *Miller v. Rep. Nat. Life Ins. Co.*, 559 F.2d 426, 428-29 (5th Cir. 1977). Even when the strength of the plaintiff's case plays a role in that evaluation, the judge considers the strength of the case before him, not a different case involving different parties that settled long ago.[17] An appellate court aptly articulated this principle when it explained why it reviewed a the trial court's decision of whether to approve a class-action settlement for an abuse

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[16] Schering Brief (ESI) at 37.

[17] Schering's class action analogy is also inapposite for the reasons set forth in Complaint Counsel's Post-Trial Brief at pages 76-78.

of discretion:[18] "Such a determination is committed to the sound discretion of the trial judge. Great weight is accorded his views because he is exposed to the litigants, and their strategies, positions and proofs. He is aware of the expense and possible legal bars to success. Simply stated, he is on the firing line and can evaluate the action accordingly." *Van Horn v. Trickey*, 840 F.2d 604, 606-07 (8th Cir. 1988). Here, we do not know the views of the district court judge who was "one the firing line" and this court cannot take his place.

Even beyond this fact, the preliminary injunction and class action analogies fail because neither requires the judge to make the precise, exacting assessment on the probabilities of either side winning that Schering seeks here. *See Van Horn*, 840 F.2d at 607 (upholding district court's approval of class action settlement despite conclusory evaluation of merits).

Schering accuses complaint counsel of rejecting its theory that an evaluation of the patent merits is necessary to assess the competitive impact of the settlements because patent cases are technical and complex. This misstates the point. Schering asks this court to undertake the impossible task of determining the outcome patent litigation, settled on an incomplete record, pursued before a different judge, with different parties and different evidence. The fact that patent litigation is admittedly complex and technical only compounds the impossibility of that task.

The outcome of the patent litigations was uncertain but the parties chose to eliminate that uncertainty by settling. This court cannot now ignore that uncertainty and reliably predict the outcome or precisely define any party's chances of winning. Therefore, the antitrust analysis must

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[18] Trial court decisions on preliminary injunction motions in patent cases are also reviewed by appellate courts for an abuse of discretion. *See Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74. F.3d 1216, 1219 (Fed. Cir. 1996).

begin with the uncontested factual predicate that the outcome of the patent litigation was uncertain.[19] Schering's evidence on the patent merits is irrelevant to that analysis.

II. THE UNDERLYING PATENT LITIGATIONS

A. Schering Has Not Proven That It Would Have Won, or Its Precise Chances of Winning

Even if one accepted Schering's premise that the outcome of settled patent litigation and the probability that one party would win that litigation could be reliably predicted, Schering has failed to prove either that it would have won, or its precise chances of winning, the Upsher and AHP patent litigations. Both Upsher and AHP prepared substantial defenses to Schering's infringement suits that rebutted every contention between the parties. Any attempt to assess the merits of the underlying litigations must focus on those contentions. Complaint counsel's technical and patent law experts also rebutted the positions taken by Schering in this proceeding regarding the patent merits.[20] For instance, complaint counsel's patent expert, Professor Adelman, testified that Upsher's arguments regarding non-infringement created so many hurdles for Schering to overcome that its likelihood of winning "approaches zero."[21] In light of this evidence, Schering's purported proof of the merits in the patent case fails.

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[19] CPF 117, 840.

[20] Indeed, the diverging views of the technical and patent law experts offered by Schering and complaint counsel in this proceeding and offered by Schering and its opponents in the underlying patent litigations further demonstrate the impossibility of predicting the likely outcome of the patent infringement suits.

[21] Tr. 15:7735 (Adelman).

B. The Applicable Law on the Infringement Issue

In the underlying patent litigations, Schering bore the burden of proving that Upsher's and AHP's products infringed the '743 patent by a preponderance of evidence. *See Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758 (Fed. Cir. 1984). Patent infringement is determined in two steps. First, the court construes the patent claims, as one of ordinary skill in the art would understand them, as a matter of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-81 (Fed. Cir. 1995) (en banc), *aff'd*, 116 S. Ct. 1384 (1996). When construing the claim, the court looks first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and the prosecution history. "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The properly construed claims are then compared to the accused device to determine whether it infringes. This second step presents a question of fact. *See Markman*, 52 F.3d at 979. To establish literal infringement, a patentee must demonstrate that every limitation set forth in a patent claim is found in the accused product, exactly. *See Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 796 (Fed. Cir. 1990).

If an accused device does not literally infringe a claim because it lacks some element of that claim, the patentee may allege infringement under the doctrine of equivalents. The accused product infringes only if contains some element that is equivalent to, or insubstantially different from, the claim element which it lacks. *See Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 35-36 (1997). Whether the substituted feature of the accused product is equivalent to the missing claim element is a question of fact. *See Southwall Tech, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). The doctrine of equivalents is not,

however, a tool for expanding the protection of a patent after examination has been completed. *See Hormone Research Foundation, Inc., v. Genetech, Inc.*, 904 F.2d 1558, 1564 (Fed. Cir. 1990).

The doctrine of prosecution history estoppel places a significant limitation on infringement under the doctrine of equivalents. Under the doctrine of prosecution history estoppel, a patentee cannot capture through the doctrine of equivalents subject matter that he surrendered during prosecution of the patent. *See Southwall Tech, Inc.*, 54 F.3d at 1580. In other words, even if an accused product has a feature that is equivalent to a missing claim element, the patentee is estopped from arguing infringement based on that equivalency if he surrendered that feature while pursing the patentability of the claim before the Patent Office. *See Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1582 (Fed. Cir. 1996). Whether prosecution history estoppel applies is a question of law. *See LaBounty Mfg., Inc., v. United States Int'l Trade Comm'n*, 867 F.2d 1572, 1576 (Fed. Cir. 1989).

C. The Schering/Upsher Litigation

1. The course of the litigation

From the beginning of its development of Upsher's generic K-Dur 20 product, Upsher was aware of and attempted to design around the '743 patent.[22] In fact, Upsher believed it had succeeded in this goal.[23] In its litigation with Schering, Upsher vigorously contested whether its product infringed •.[24]

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[22] CPF 90.

[23] CPF 91.

[24] CPF 100-01.

The '743 patent describes and claims a controlled-release potassium chloride tablet containing potassium chloride crystals coated with specified coating material. The patent explains that other controlled-release potassium chloride dosage forms were known, but that the coating material described in the '743 patent provided certain advantages.[25] All claims of the '743 patent, including claim 1 require, at a minimum, a pharmaceutical dosage unit in tablet form comprising the elements (a) potassium chloride crystals and (b) a coating material for the crystals, wherein the coating material includes a mixture of ethylcellulose ("EC") having a viscosity greater than 40 centipoise ("cp") along with hydroxypropylcellulose ("HPC") and/or polyethylene glycol (PEG).[26]

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[25] CX 12 at FTC 0021319-21321 (the '743 patent).

[26] CPF 102; CX 12 at FTC 0021322-23 (the '743 Patent).

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. . . . . [31] The parties settled the evening of the hearing on Upsher's summary judgment motion, before the court could rule.[32]

2. Schering has not proven that it could overcome Upsher's prosecution history estoppel argument

An evaluation of Upsher's prosecution history estoppel argument requires a thorough review of the prosecution history (the patent applicant's negotiation with the Patent Office) of the '743 patent. The '743 patent matured from patent application no. 830,981 (the '981 application). The claims which Schering originally filed in the Patent Office required, at a minimum, a pharmaceutical dosage unit comprising (a) potassium chloride crystals and (b) a coating material for the crystals, wherein the coating material includes EC and HPC or PEG.[33] Thus, the differences between the claim as originally submitted and claim 1 as issued in the '743 patent is that claim 1 as issued includes the additional limitations that the dosage unit is a tablet and the EC must have viscosity of greater than 40 cp. The reasons that Schering added those limitations, and

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[31] . . . . . .

[32] . . . . . .

[33] CX 647 at USL PLD 001592 (the '743 Patent's Prosecution History).

in particular the limitation requiring EC to have a viscosity of 40 cp, form the basis of Upsher's powerful argument that its product did not infringe the '743 patent.

Following an initial review of the '981 application claims as originally filed, the patent examiner rejected all claims for "obviousness-type double patenting" in light of U.S. Patent No. 4,555,399 ('399 patent). The '399 patent (which has the same inventor as the '743 patent, Charles Hsiao) claims a tablet comprising aspirin crystals coated with a mixture of EC and HPC.[34] In making his rejection the examiner stated "the substitution of potassium chloride for aspirin in the same formulation would appear to be at least prima facie obvious."[35] In other words, the examiner took the position that the coatings of the '399 patent and the '981 application were the same, and that it was obvious to apply that coating to potassium chloride rather than aspirin.

Schering responded by arguing that its claimed potassium chloride product was not obvious due to "the widely varied properties and uses" of potassium chloride and aspirin.[36] The examiner rejected this argument and again rejected the pending claims in light of the '399 patent. The examiner explained:[37]

> Hsiao, (U.S. 4,555,399) filed Nov. 18, 1983, is a fully available prior art reference to the identical coating (E.C. and H.P.C.), for the identical purpose (lessened irritant effect on the gastric mucosa, with a different gastric irritating drug: aspirin (A.S.A.) instead of potassium chloride (KCl). The difference is obvious . . . .

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[34] CX 647 at USL PLD 001682-001684 (the '399 Patent in the '743 Prosecution History).

[35] CX 647 at USL PLD at 1601-02 ('743 Prosecution History).

[36] CX 647 at USL PLD at 1610 ('743 Prosecution History).

[37] CX 647 at USL PLD at 1639 ('743 Prosecution History).

In response to this rejection, Schering amended pending claim 1 by adding the limitation "said ethycellulose has a viscosity of greater than 40 cp."[38] Schering then argued to the examiner that the 40 cp limitation distinguished its claimed invention from the '399 patent:[39]

> In rejecting the claims it is alleged that it would be prima facie obvious to replace a different gastric irritating drug, e.g. potassium chloride, for the aspirin in the cited ['399] patent. It is submitted that the mere substitution of potassium chloride for aspirin in the prior art tablet formulation would not result in the present invention. A careful analysis of the Hsiao ['399] patent would not lead one skilled in the art to utilize an ethylcellulose polymer having a viscosity greater than 40 cp and preferably an viscosity of about 85-110 cp to produce a sustained release potassium chloride tablet. The Hsiao ['399 patent] at column 2, lines 17-38, discloses that the major component of the polymeric coating used in coating the aspirin material is ethylcellulose, however, there is no teaching or indication as to the type or grade of ethylcellulose that can be utilized in preparing the aspirin tablet of the invention. The only information of the type or grade of ethylcellulose used in preparing the coated aspirin material is in Example 1 (column 3, lines 7-8) wherein it is stated that the ethylcellulose is "Ethocel N-10 (Dow)." The grade of ethylcellulose utilized in practicing the present invention is important to obtain potassium chloride tablets exhibiting controlled release properties.

Thus, Schering argued that its claims were patentable over the '399 patent because it used EC with a viscosity greater than 40 cp and that this feature of its invention was "important." In describing its invention Schering further stated, "[a]pplicant's invention requires coating of potassium chloride with specific ethylcellulose and polyethylene glycol followed by compression into tablets."[40] . . . . . .

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[38] CX 647 at USL PLD at 1642 ('743 Prosecution History).

[39] CX 647 at USL PLD at 001644-45 ('743 Prosecution History) (emphasis added).

[40] CX 647 at USL PLD at 001646 ('743 Prosecution History).

[redacted][41] Following these arguments, the examiner allowed the claims of the '743 patent, including the limitation that the viscosity of the EC be greater than 40 cp, without comment.[42]

[redacted][43]

[redacted]

[redacted]

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[41] [redacted]

[42] CX 647 at USL PLD at 001650 ('743 Prosecution History).

[43] [redacted]

[redacted][44][redacted]

[44] Several of the cases relied by Schering in its discussion of prosecution history estoppel at pages 6-7 of Attachment A to its post-trial brief regarding the Upsher settlement were decided after the June 1997 settlement and, therefore, would not have influenced the outcome of Schering/Upsher litigation.

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. . He also testified that Schering could have argued, without adding the limitation to 40 cp, that the potassium chloride in its invention was so different from the aspirin in the '399 patent that the '399 patent did not render its invention obvious. Tr. 32:7718 (Adelman).

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3. Schering has not proven that it would have prevailed on the issue of whether . . . . is equivalent to HPC

The claims of the '743 patent require that the coating material contain either hydroxypropyl cellulose (HPC) or polyethylene glycol (PEG). . . . . .

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. . . . . .[49] One test for examining whether a feature of an accused product is insubstantially different from the missing claim element is to determine whether both provide substantially the same function, in the same way, to give the same result. *See Hilton Davis Chemical Co v. Warner-Jenkinson Co., Inc.*, 62 F.3d 1512, 1518 (Fed. Cir. 1995) (en banc), *rev'd on other grounds*, 520 U.S. 17 (1997).

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[51] [illegible]

[52] [illegible]

[53] [illegible]

[54] [illegible]

[55] [illegible]

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[51] [illegible]

[52] [illegible]

[53] [illegible]

[54] [illegible]

[55] [illegible] He also acknowledged that HPC promotes permeability in the '743

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invention. Tr. 14:3067-68, 3073-74 (Banker).

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. . . . . If the district court in the underlying litigation had sided with Upsher on this hotly contested, highly technical and factually intensive issue, Upsher would have won the litigation. In spite of this, Schering argues that the evidence on this issue favors it to such a degree that this court can determine that Schering had a "strong case" and precisely weigh the probability that it would have won. Because Schering's evidence ignores Upsher's challenges and

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[58] Dr. Christopher Rhodes is a Professor of Applied Pharmaceutical Sciences at the University of Rhode Island. He is co-editor of the text *Modern Pharmaceutics* with Schering's expert, Dr. Banker. . . . . Schering's heavy reliance on the fact that Dr. Banker declined to serve as Upsher's expert ignores the fact that a pre-eminent scientist in the field, Dr. Rhodes, did serve as Upsher's expert and disagreed with the opinions espoused by Dr. Banker.

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Dr. Banakar's testimony, it fails to demonstrate with the required certainty and precision how the court in the underlying litigation would have decided this issue.[61]

4. ***Schering failed to prove that EC with a viscosity of • • is equivalent to EC with a viscosity greater than 40 cp***

The claims of the '743 patent require that the coating material contain ethylcellulose ("EC") having a viscosity greater than 40 cp. •
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• • • • • • • • • • • • • • • •[62] This issue, like those discussed above, was dispositive. Schering had to win this point in order to demonstrate infringement.

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In light of these overwhelming flaws in Schering's evidence, Schering has not demonstrated that it had any significant chance of success on this issue in the underlying patent litigation.[68]

D. Both Upsher and AHP Challenged the Validity and Enforceability of the Patent

Even if Schering had demonstrated infringement by Upsher, it still had to successfully defend its challenges to the validity and enforceability of the' 743 patent in order to win the underlying patent litigations. A patent is invalid if the claimed subject matter "would have been obvious at the time the invention was made to a person having ordinary skill in the art" to which the patent pertains. 35 U.S.C. § 103. A claim may be obvious in view of a combination of prior art references that together disclose the claimed features if something in the references or the level of skill in the art suggest their combination. *See SmithKline Diagnostics, Inc., v. Helena Labs.*

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Corp., 859 F.2d 878, 886-887 (Fed. Cir. 1988). A patent is unenforceable if it was procured through inequitable conduct before the Patent Office. Inequitable conduct includes intentional affirmative misrepresentations of a material fact, submission of false material information or failure to disclose material information to the patent examiner. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995).

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AHP's technical expert, Dr. Hopfenberg, was prepared to offer similar arguments.[72] Moreover,

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[72] SPX 693* at ESI EXP 000728-735 (Expert Report of Dr. Harold Hopfenberg).

Schering's patent expert in this proceeding, Mr. Miller, believes the district judge in the AHP patent litigation expressed concern over the validity of the patent during the *Markman* hearing.[73]

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The district court never addressed the invalidity and unenforceability issues.[76] Schering has not demonstrated that it would have prevailed on these issues. It has offered only the conclusory opinion testimony of Mr. Miller that he considered these defenses weak. This does

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[73] Tr. 15:3388-89 (Miller).

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[76] CPF 116, 837.

not and cannot offer any evidence for predicting the decision of the district court judge presiding over the underlying litigation, as is necessary if one wishes to assess whether Schering was likely to win that litigation.

E. Mr. Miller Can Offer No Opinion on Technical Factual Issues

Upsher needed to win on only one of the issues discussed above in order to win the entire litigation. Therefore, assessing the strength of Schering's case requires assessing each of these issues: prosecution history estoppel, [redacted], the validity of the '743 patent and the enforceability of the '743 patent. The issues of equivalency, validity and enforceability, and therefore any evaluation of the outcome of the patent litigation, involves determinations of highly technical factual issues. In spite of this, Schering offers the opinion of a patent attorney, whose expertise does not encompass these technical issues, on the strength of its patent case.

Even if the infirmities in Mr. Miller's testimony discussed above (its unreliable and speculative nature) could be overcome (and they cannot), Mr. Miller did not and cannot provide the opinion on the relative strength of the patent merits and the likely outcome of the patent litigations that Schering now ascribes to him. [redacted][77] The court prevented his attempt to do so.[78] Mr. Miller is not qualified to give either his own views on

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[77] [redacted]

[78] Tr. 15:3304-06, 3392-93 (Miller).

the relative strength of the parties' arguments on these questions, or to predict the views of the district courts hearing the evidence. Without an assessment of these dispositive issues, Mr. Miller's views on the relative merits of the patent litigations or the likelihood of Schering prevailing are utterly meaningless. The majority of the opinions he offered in this proceeding were nothing more than the syllogism, "if Schering is correct on the technical issues, then Schering had a strong case."

With regard to these highly technical and dispositive factual issues, Schering presented the testimony of its technical expert, Dr. Banker, who opined that the positions taken by Schering in the underlying patent litigation were factually correct. •[79] Dr. Banker is clearly not qualified to offer such an opinion.

Schering faces a conundrum in trying to show the likely outcome of the underlying patent litigation. Its patent expert cannot form an opinion on the merits of the technical factual issues because technical issues fall outside the scope of his expertise. Its technical expert cannot form an opinion on how a court would have decided any issue, even technical factual issues, because the applicable legal tests are outside the scope of his expertise. This conundrum aptly illustrates the impossibility of Schering's attempts to predict the outcome of settled litigation. Reliable, proper evidence on the issue is simply not available. The antitrust analysis of the agreement must begin from the basis that the outcome of the litigation was uncertain.

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F. The Schering/AHP Litigation

1. The course of the litigation

AHP prepared a comprehensive defense to Schering's allegations of patent infringement. AHP's Answer included the affirmative defenses and counterclaims that AHP did not infringe the '743 patent and that the patent was invalid and unenforceable. AHP also included a counterclaim for unfair competition, based on the allegation that Schering's suit against AHP was objectively unreasonable and filed solely for the purpose of triggering the 30-month stay under the Hatch-Waxman Act.[80]

AHP's defense to Schering's infringement allegation consisted of two parts. First, AHP maintained that claim 1 of the '743 patent required a coating material containing a layer which was a mixture of EC and either HPC or PEG present in the recited proportions. Second, AHP contended that the EC and the HPC in its coating material were not mixed.[81] The district court in the underlying patent litigation held a "*Markman*" hearing on the issue of claim construction. The purpose of a *Markman* hearing is for a court to hear testimony and argument on the proper interpretation of patent claims to aid its own determination, as a matter of law, on the meaning of those claims.[82]

The court dismissed the Schering/AHP patent infringement action on January 26, 1998, four days after the *Markman* hearing, pursuant to the settlement agreement between the parties.

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[80] CPF 823-824.

[81] CPF 827.

[82] Tr. 15:3326-27 (Miller).

The court never issued a ruling on claim interpretation and the parties never commenced trial.[83] AHP would have won the litigation if Schering did not carry its burden of proving infringement or if AHP demonstrated that the patent was invalid or unenforceable. At the time of the Schering/AHP Agreement, Schering believed that it was possible that AHP could win the patent litigation.[84]

2. Claim interpretation

Claim 1 of the '743 patent recites (with emphasis added to the relevant portions):

> A pharmaceutical dosage unit in tablet form for oral administration of potassium chloride, comprising;
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> a plurality of coated potassium chloride crystals, the amount of potassium chloride being in the range of about 65% to about 86.5% by weight based on the total weight of the dosage unit;
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> a coating material for the individual potassium chloride crystals, the coating material comprising
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> ethylcellulose in the amount in the range of about 9% to about 15% by weight based on the total weight of the coated crystals
>
> and at least one member selected from hydroxypropycellulose and polyethylene glycol in an amount in the range of about 0.5% to about 3% by weight based on the total weight of the coated crystals and said ethylcellulose has a viscosity greater than 40 cp.

The central claim interpretation issue in the AHP patent litigation focused on whether the term "a coating material" as used in the claim required that the two listed components, EC and either HPC or polyethylene glycol, be mixed. AHP took the position that the claim required that the EC and HPC be mixed. Schering took the position that "a coating material" could be

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[83] CPF 831.

[84] CPF 839-40.

comprised of a separate layer of EC and a separate layer of HPC. The testimony at the *Markman* hearing addressed this issue.[85]

Schering now maintains that AHP had "little chance" of winning the debate over the proper interpretation of the claim term "a coating material" before the district court. Schering does not tell us, however, whether it held that belief at the time of settlement, after hearing the judge's and magistrate's comments on the merits. In particular, after Schering and AHP had submitted evidence at the *Markman* hearing, Judge Du Bois stated that the case was "not a slam-dunk case," and that he had not made up his mind.[86] Moreover, in private meetings with AHP, Magistrate Judge Reuter told AHP that he thought AHP had somewhat the better of the infringement case.[87]

Instead, Schering cites to recent case law – which could have no bearing the outcome of the Schering/AHP patent litigation because it had not yet been decided – to support its argument that the term "a coating material" should be given its "ordinary meaning" as supported by a specialized technical dictionary. In particular, Schering relies on the definition of the verb "coating" in the *Dictionary of Pharmacy* as meaning "covering a tablet or pill with one or more protective layers," even though the term at issue is not the verb "coating" but the noun, "a coating material." Schering does not respond to many of the arguments raised by AHP in the underlying litigation and adopted by complaint counsel's technical expert, Dr. Banakar, rebutting this point.

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[85] CPF 829.

[86] Tr. 14:3037-39 (Banker); SPX 687* at ESI HRG 000127 (Transcript of *Markman* hearing in *Key v. ESI*).

[87] CX 1482† at 61:3-8, 62:9-22, 65:14-18 (Alaburda IH).

In the underlying litigation, AHP disputed Schering's argument that the plain meaning of "a coating material" comprising defined proportions of EC and HPC allowed for a separate layer of EC and HPC. AHP contended that the "a" in "a coating material" clearly refers to a single coating material, and that for a single material to contain two ingredients, those ingredients must be mixed. According to AHP, for a product to fit within the plain meaning of the claim language, it must have at least one coating layer containing a complete mixture of EC and HPC in the required proportions.[88]

It is axiomatic that claims must be interpreted in light of the specification and patent prosecution history. *Vitronics Corp.*, 90 F.3d at 1583. It is improper to interpret claims without considering the specification.[89] To support its proposed claim interpretation, AHP explained that the '743 patent specification only described a coating material in which the EC and HPC were completely mixed. Schering does not dispute this.[90] In particular, AHP discussed several portions of the patent that demonstrated mixing, including: (1) the patent's description of the invention as potassium chloride crystals which are coated with "a polymeric mixture;" (2) the patent's description of a manufacturing process which applies "a controlled and uniform coating" and which can only result in mixing; and (3) the patent's description of the importance of "providing the proper balance of EC and HPC" in "a polymer film" in order to obtain the invention's sustained release properties -- a reference to the HPC's forming channels when mixed with the

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[88] SPX 687* ESI PLD 002265-66 (Reply Memorandum in Support of ESI's Motion for Summary Judgment).

[89] Tr. 15:3398 (Miller).

[90] Tr. 14:3119-21 (Banker).

EC.[91] At the *Markman* hearing, AHP's technical expert, Dr. Hopfenberg also testified, based on these points, that one of ordinary skill in the art would interpret the claims to require a coating material in which the EC and HPC were mixed.[92]

AHP also explained that it had obtained U.S. Patent No. 5,422,122 claiming its product, potassium chloride crystals coated with a separate layer of EC and then a layer of HPC. According to AHP, the patent examiner expressly considered the '743 patent during examination of the '122 patent and determined that the '122 patent was different than the '743 patent because that patent requires mixing of the EC and HPC, whereas the '122 patent did not.[93] AHP argued that the examiner's views were evidence of the proper interpretation of the claim.

At trial in this proceeding, complaint counsel provided the testimony of its technical expert, Dr. Banakar, on the question of the proper interpretation of "a coating material." Dr. Banakar concurred with the opinions of Dr. Hopfenberg, and disagreed with those of Dr. Banker and Mr. Miller, when he explained that "a coating material" requires mixing of the EC and HPC.[94] This testimony that AHP had the better position in the underlying patent litigation provides direct rebuttal to the opinions of Dr. Banker and Mr. Miller on the merits of the underlying litigation.

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[91] SPX 687* at ESI PLD 001652-57 (ESI's Motion for Summary Judgment of No Literal Infringement); SPX 687* ESI PLD 002267-68, 002269-70 (Reply Memorandum in Support of ESI's Motion for Summary Judgment).

[92] SPX 687* at ESI HRG 000021-0025, 000053-0059 (Transcript of *Markman* Hearing in *Key v. ESI*).

[93] SPX 687* at ESI PLD 001657, 001665 (ESI's Motion for Summary Judgment of No Literal Infringement); SPX 687* ESI PLD 002271 (Reply Memorandum in Support of ESI's Motion for Summary Judgment).

[94] Tr. 26:6387-89 (Banakar).

Moreover, because claims are interpreted as understood by one skilled in the art,[95] Dr. Banakar's views on claim interpretation are more probative of their meaning than are the views of Mr. Miller, which, because he is not skilled in the art, are irrelevant. Schering's contention that complaint counsel has not rebutted its arguments regarding the AHP matter are simply false.

As this court can determine from the patent, its prosecution history, and the testimony of Dr. Banakar, Schering's claim construction requires the nonsensical conclusion that two separate and distinct layers, each composed of a different material is not two materials, but one. Schering reaches that point only by ignoring "the most significant source of the legally operative meaning of disputed claim language," the specification. *Vitronics Corp.*, 90 F.3d at 1582. Schering has failed to demonstrate that the court in the underlying patent litigation would have adopted its claim interpretation.

3. Schering has not demonstrated that the HPC and EC in AHP's product was completely mixed in the required amounts

If the court had adopted AHP's claim interpretation, by holding that the claims required a coating material comprised of a mixture of EC and HPC in specified proportions, Schering would have had the burden of demonstrating at trial that these two components of AHP's coating material were mixed in those proportions in order to prove literal infringement. *See SmithKline Diagnostics Inc. v. Helena Lab. Corp.*, 859 F.2d 878, 889 (Fed. Cir.1988) (patentee's burden to establish infringement by a preponderance of the evidence). This issue presents a question of fact. *See Engel Indus. v. Lockformer Co.*, 96 F.3d 1398, 1406 (Fed. Cir. 1996).

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[95] *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 986 (Fed. Cir. 1995).

Schering took the position in the underlying patent litigation that even some mixing at the interface of the EC and HPC layers in AHP's product would be sufficient to constitute infringement.[96]

AHP responded that Schering offered no evidence that the amount of mixing it alleged was sufficient to satisfy the claim limitation that there be one coating material with complete mixing of EC and HPC in the required amounts (9-15% EC and 0.5-3% HPC). To support this point, AHP cited the deposition testimony of Dr. Langer in which he admitted that he could not quantify how much HPC might be mixed into the EC layer in AHP's product.[97] In this proceeding also, Dr. Langer admitted that he could not testify that the EC and HPC in AHP's coating were completely mixed. He was only willing to estimate that they were about 50% mixed.[98] He also admitted that the SEM, FTIR and DSC studies did not allow him to quantify the degree of any mixing.[99] Even in its brief in this matter, Schering only states that there was "significant" mixing.

As AHP asserted, this deficiency in Schering's evidence dooms its argument that if the court had adopted AHP's claim interpretation, it still could have demonstrated literal infringement. The claim interpretation proposed by AHP required that the HPC and EC be completely mixed so that it became one coating material containing HPC and EC in the amounts specified in the claims. Schering could not prove literal infringement with a general statement

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[96] SPX 687* at ESI PLD 002476 (Schering's Reply Memorandum in Support of its Cross-Motion for summary Judgment of Infringement.).

[97] SPX 687* at ESI PLD 00345-46 (ESI's Surreply in Support of its Motion for Summary Judgment).

[98] Tr. 13:2856-57 (Langer).

[99] Tr. 13:285253, 2855-56 (Langer).

that there was "some" mixing. It needed to demonstrate that the mixing satisfied the claims, but it lacked this evidence. Thus, if the court had adopted AHP's claim interpretation requiring complete mixing, or mixing to form a coating containing EC and HPC in the specified amounts, Schering could not have established literal infringement.[100]

AHP went beyond this fatal flaw in Schering's infringement argument, and contested that its EC and HPC were not mixed. Dr. Hopfenberg first explained that AHP's manufacturing process produced distinct EC and HPC layers. According to Dr. Hopfenberg, to make its generic product, AHP first deposited a pure layer of EC over the potassium chloride crystals by a liquid phase process known as coacervation.[101] In the second coating step, AHP deposited a pure layer of HPC over the EC by spray-coating to create a second and distinct layer. This contrasts with the fluidized bed spray-coating process of the '743 patent, which, as described by Dr. Hopfenberg, produces a homogeneous mixture of EC and HPC. He also explained that coacervated EC, free from HPC, could supply sustained release.[102]

Schering relies on Dr. Langer's experiments to show mixing in AHP's product. AHP rebutted this evidence through its experts, Dr. Hopfenberg and Mr. Butler. They disputed Dr. Langer's scanning electron micrograph (SEM) studies and presented their own. Dr. Hopfenberg stated that his studies, which gave a more accurate "picture" of the cross-section of AHP's

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[100] Tr. 15:3397 (Miller).

[101] Dr. Hopfenberg explained that in the process of coacervation, particles of the drug are dispersed in a solution comprising cyclohexane, EC and a phase inducer, polyethylene. Through heating and agitation, both polymers, EC and polyethylene, dissolve in the solvent, cyclohexane. When the temperature is lowered, the EC condenses on and encapsulates the drug. SPX 693* at 000723-24 (Expert Report of Dr. Harold Hopfenberg).

[102] SPX 693* at ESI EXP 000723-726 (Expert Report of Dr. Harold Hopfenberg).

product, illustrated that it had an inner layer of EC and a second, thinner outer layer of HPC.[103]

Complaint counsel's technical expert, Dr. Banakar, concurred with the opinion of AHP's technical experts that the EC and HPC in AHP's coating were not mixed.[104] Dr. Banakar testified that at least one of the SEMs that Dr. Langer took of a cross section of the AHP tablet, showed that the AHP tablet was not coated with a uniform mixture of EC and HPC.[105]

In addition, Dr. Banakar testified that the dissolution studies by Dr. Hopfenberg show that HPC dissolved rapidly from the AHP tablet, clearly indicating that the HPC forms a distinct outer layer over the EC inner layer.[106] He testified that Dr. Langer made a fundamental error in relying on USP dissolution tests to draw a conclusion that EC and HPC were mixed, because the USP test is intended to be used to measure dissolution of an active ingredient (e.g. potassium chloride) from a finished dosage form rather than dissolution of an excipient, like HPC.[107] Therefore, Dr. Langer's dissolution test does not provide meaningful evidence of mixing.

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[103] SPX 687* at 00345 (AHP's Surreply in Support of its Motion for Summary Judgment); SPX 695* at ESI EXP 000753-765 (Expert Report of Dr. Harold Hopfenberg and Mr. William O. Butler).

[104] Tr. 26:6387-92, 6405-06 (Banakar); CPF 832.

[105] Tr. 26:6387-92 (Banakar); CPF 832. Ironically, Schering criticizes Dr. Banakar for relying on copies of the SEM's rather than original micrographs. Schering was never able to locate the originals and provide them for Dr. Banakar's review. *See* CPRF 3.542. If copies are insufficient for evaluating whether the EC and HPC are mixed, then Schering must be prohibited from relying on them, and on Dr. Langer's testimony in this proceeding, which was based entirely on copies, as evidence of mixing.

[106] Tr. 26:6407-09 (Banakar). Dr. Langer acknowledged that quick dissolution of the HPC could demonstrate the absence of mixing. Tr. 13:2891 (Langer).

[107] Tr. 26:6409-10 (Banakar).

Dr. Langer's SEM, FTIR and DSC studies were also flawed. He did not follow basic scientific practice and perform control experiments with either products known to have separate EC and HPC layers or with a product known to have a coating material of mixed EC and HPC, such as K-Dur.[108] Moreover, he admitted that he could not explain the source of the "fingerprint" in the FTIR that he claimed was caused by mixing.[109] Dr. Langer also acknowledged that he had not previously used DSC to examine the interface of one polymer on another.[110] Thus, complaint counsel has shown the untrustworthiness of the Dr. Langer's tests.

In light of these arguments raised by AHP and complaint counsel, including the attacks on Schering's evidence, Schering has not neither demonstrated that it would have won the Schering/AHP patent litigation nor demonstrated the probabilities of the outcome with the precision required to make a meaningful comparison with the split of the patent life.

4. Infringement under the doctrine of equivalents

If Schering had failed to prove literal infringement because the EC and HPC of AHP's product were present in separate layers, it might have attempted to prove infringement under the doctrine of equivalents at trial by demonstrating that AHP's EC and HPC coatings were equivalent to, or insubstantially different than, the patented, mixed coating material. Whether AHP's coatings were equivalent to the patented coating material is a question of fact. *See Engel Indus.*, 96 F.3d at 1406.

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[108] Tr. 13:2823-24, 2855 (Langer).

[109] Tr. 13:2869-70 (Langer).

[110] Tr. 13:2880-81 (Langer).

AHP's technical expert, Dr. Hopfenberg, was prepared to testify at trial during the Schering/AHP patent litigation that AHP's separate layers were substantially different from the coating material claimed by the '743 patent.[111] Dr. Hopfenberg explained that the coacervation technique used to apply EC in AHP's product produces an EC layer that is substantially different from the EC and HPC mixture disclosed in the '743 patent. The EC layer in AHP's coating material, which lacks the channels formed by HPC in the EC of the patented product, provides sustained release of the potassium chloride in a different way than the patented coating material. AHP's product provides sustained release as a result of the characteristics imparted by the coacervation process. According to Dr. Hopfenberg, the HPC in AHP's product functions only as a binder and does not form channels. When the product is swallowed, the HPC outer layer quickly dissolves and so has no effect.[112] Dr. Banakar agreed that the EC coating of the AHP product worked to provide sustained release in a different way than the mixed coating material of the patented product.[113]

If the district judge had accepted Dr. Hopfenberg's position that the AHP product was substantially different from the claimed invention in the '743 patent, then if would have found that AHP did not infringe the '743 patent under the doctrine of equivalents. Given the disagreement between the experts on this matter, Schering has not demonstrated the strength of

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[111] SPX 693* at ESI EXP 000723-728, 000697-700 (Expert Reports of Dr. Harold Hopfenberg).

[112] SPX 693* at ESI EXP 000724-725, ESI EXP 000697-700 (Expert Reports of Dr. Harold Hopfenberg); CPF 835.

[113] Tr. 26:6387-92 (Banakar).

its position under the doctrine of equivalents or the precise probability that it would win the underlying litigations.

E. Mr. Miller's opinion is rebutted

Schering claims to have proven that it would have won its patent litigation with AHP. It relies on Mr. Miller's opinion that its case against AHP was "very strong." Schering also asserts that complaint counsel called no witness to rebut Mr. Miller's opinion.[114] This is simply untrue.

Assessing the strength of Schering's case requires assessing each of the issues above: claim interpretation, whether AHP's coating had mixing, the equivalency of AHP's coating with the patented version, the validity of the '743 patent and the enforceability of the '743 patent. As in the Upsher case, the issues of mixing, equivalency, validity and enforceability, and therefore any evaluation of the outcome of the patent litigation, involves determinations of highly technical factual issues. In spite of this, Schering offers the opinion of a Mr. Miller, whose expertise does not encompass these technical issues, on the strength of its patent case. Mr. Miller's assessment of the patent merits is not meaningful and requires no direct rebuttal.

Complaint counsel has offered the testimony of a person qualified to opine on the technical issues in the patent litigations, Dr. Banakar. He has provided opinions on claim interpretation, infringement and equivalency that directly rebutted the opinions of Dr. Banker and Mr. Miller.[115]

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[114] Schering Brief (ESI) at 33-34.

[115] Tr. 26:6387-92, 6405 (Banakar). *See also* CPRF 3.502, 3.507, 3.516, 3.558, 3.562

III. CONCLUSION

It is simply not possible for this court to reliably determine who would have won the underlying patent litigation. The outcome was uncertain at the time of the settlement and any antitrust analysis of the settlement agreements must begin from a basis that accepts that uncertainty. Moreover, it is not possible to reliably assign a probability to one side's chances of winning with the degree of precision required to make any comparison of the probabilities and the split of the patent life meaningful.

However, even if the court were to undertake these tasks, Schering has failed to demonstrate either that it would have won the litigations or its precise probability of winning. The unanswered arguments raised by Upsher and AHP, and the evidence presented by complaint counsel, prevent Schering from making such a showing.

CERTIFICATE OF SERVICE

I, Pamela L. Timus, hereby certify that on May 14, 2002, I caused two copies of the "Public Version" of the following:

- Complaint Counsel's Reply to Schering-Plough's Proposed Findings of Fact Relating to the Settlement with ESI-Lederle
- Complaint Counsel's Reply to Schering-Plough's Proposed Findings Relating to the Underlying Patent Cases
- Complaint Counsel's Reply to Schering-Plough's Proposed Findings of Fact Relating to the Settlement with Upsher-Smith (Volumes 1 & 2)
- Complaint Counsel's Reply Brief
- Complaint Counsel's Reply to Schering-Plough's Proposed Economic and Policy Findings
- Complaint Counsel's Reply to Upsher-Smith's Proposed Findings of Facts (Volumes1 thru 3)

to be served by hand delivery upon:

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

and one copy upon the following persons via Federal Express:

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