United States of America

FEDERAL TRADE COMMISSION

Docket No. 9297

IN THE MATTER OF

SCHERING-PLOUGH CORPORATION,
A CORPORATION,

UPSHER-SMITH LABORATORIES, INC.,
A CORPORATION,

AND

AMERICAN HOMES PRODUCTS CORPORATION,
A CORPORATION.

ANSWERING BRIEF OF UPSHER-SMITH LABORATORIES, INC.

PUBLIC VERSION

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October 3, 2002

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GLOSSARY OF ABBREVIATIONS

Abbreviation	Document or Reference
ID	Initial Decision
IDF	Initial Decision Finding of Fact
USX	Upsher-Smith Exhibit
CX	Complaint Counsel Exhibit
SPX	Schering-Plough Exhibit
UPF	Upsher-Smith's Proposed Findings of Fact
CPF	Complaint Counsel's Proposed Finding of Fact
SPF	Schering's Proposed Findings of Fact
UR-CPF	Upsher-Smith's Rebuttal to Complaint Counsel's Proposed Findings of Fact
CR-UPF	Complaint Counsel's Rebuttal to Upsher-Smith's Proposed Findings of Fact
CR-SPF	Complaint Counsel's Rebuttal to Schering's Proposed Findings of Fact
SR-CPF	Schering's Rebuttal to Complaint Counsel's Proposed Findings of Fact
UTB	Upsher-Smith's Trial Brief
UPTB	Upsher-Smith's Post-Trial Brief
UR-PTB	Upsher-Smith's Post-Trial Rebuttal Brief
CCSC	Complaint Counsel's Statement of Case
CCTB	Complaint Counsel's Trial Brief
CPTB	Complaint Counsel's Post-Trial Brief
CR-PTB	Complaint Counsel's Post-Trial Rebuttal Brief
CC-UMD	Complaint Counsel's Corrected Memorandum in Opposition to Upsher-Smith's Motion to Dismiss
CAB	Complaint Counsel's Appeal Brief

- Citations to hearing transcripts are by page number: (Tr. 7491).
- Citations to transcripts of live witness testimony indicated by witness's name: (Freese 2451:12-14).
- Citations to *in camera* material contained in documents, testimony, and findings are designated by highlighting, braces, and the notation "(*in camera*)" following the citation: { } (CX 339 (*in camera*)).

INTRODUCTION

The Schering/Upsher-Smith settlement allowed Upsher-Smith to introduce Klor-Con M-20, its AB-rated generic, more than five years before the expiration of Schering's patent. At the time of the settlement, June 1997, Hatch-Waxman's thirty-month stay legally precluded Upsher-Smith from entering the market. In addition, the specter of huge patent-infringement liability guaranteed that Upsher-Smith would stay off the market at least for the duration of the litigation — probably years — and, if Schering were to prevail in the litigation, for nearly a decade until Schering's patent expired on September 5, 2006.

The settlement effectively cut more than half the remaining life off Schering's patent. It removed the litigation's cloud of uncertainty, thereby allowing Upsher-Smith to dramatically expand its manufacturing facilities and to conduct a massive and successful new product launch on September 1, 2001.

Thanks to the settlement, today consumers enjoy the choice of several AB-rated generic alternatives to K-Dur 20. Without the settlement, there likely would be none.

Despite the numerous procompetitive benefits of the settlement, Complaint Counsel charge that it was illegal. This charge is based on a novel test Complaint Counsel's economist, Timothy Bresnahan, developed especially for this case. Under this "Bresnahan Test," a patent settlement is "anti-competitive" only if (1) there is a "reverse payment" of "net positive value" to the potential entrant and (2) the patent holder has "monopoly power." (Bresnahan 654:15-655:6). Bresnahan was unequivocal that ***both*** of the elements had to be met before a settlement could be condemned as "anti-competitive." After forty days of trial, with forty-one live witnesses and thousands of exhibits, the evidence at trial established that ***neither*** element could be met.

Instead of a "reverse payment," the evidence proved that Schering and Upsher-Smith settled the patent litigation by cutting five years off the remaining life of Schering's patent, and that they entered into a *bona fide*, efficiency-enhancing licensing transaction for fair value. Bresnahan and Complaint Counsel had conceded that such a settlement and side deal would ***not*** be anticompetitive. In his 121-page Initial Decision, Judge Chappell meticulously sets forth the evidence establishing that Schering's $60 million in royalty payments was fair value for the rights to Niacor-SR and the five other products it licensed from Upsher-Smith.

In their appeal brief, Complaint Counsel argue that Judge Chappell näively credited self-serving testimony that was contradicted by contemporaneous documents. (CAB:1-2, 23). In fact, he did no such thing. Judge Chappell not only scrutinized the live witnesses appearing before him, evaluating their demeanor and credibility, but he also carefully assessed how the testimony squared with the documentary record. This exercise ultimately led the Judge to conclude that the contemporaneous documents ***corroborated*** the testimony of witnesses: "The fact testimony at trial was unrebutted and credible in establishing that the licensing agreement was a *bona fide* arms-length transaction, and that Schering's royalty payments to Upsher-Smith were payments for the products being licensed to Schering, together with certain production rights. Contemporaneous documentary evidence, such as Mr. Audibert's commercial assessment and Schering's Board Presentation, corroborated that testimony." (ID 107). Judge Chappell saw and heard the witnesses; he assessed their demeanor and credibility; this was his unbiased conclusion.

To support their contention that Schering made a "reverse payment," Complaint Counsel relied principally upon Dr. Nelson L. Levy's conclusory opinion that Schering paid more than fair value for Niacor-SR. After hearing Levy, Judge Chappell concluded that his opinion was

"contradicted by the greater weight of the evidence," observing that Levy (i) "performed no quantitative analysis" of Niacor-SR or the five other products, (ii) "did not consider the market value of KOS," a publicly traded company that manufactured a product similar to Niacor-SR, (iii) "lacked expertise in the area of cholesterol-lowering drugs and niacin," and (iv) was "rebutted" and "discredited" by evidence he failed to review. (ID 109; IDF 290-318).

To prove that Schering was a monopolist, Complaint Counsel relied exclusively on Bresnahan. But Bresnahan simply ***assumed*** that K-Dur 20, as a branded drug covered by a patent, was a monopoly product. This is not antitrust law or economic analysis; indeed, it is axiomatic that a patent or brand does ***not*** create an antitrust monopoly. Bresnahan did not perform any price studies, market studies, cross-elasticity studies, econometrics or any other statistical analyses comparing the price of K-Dur 20 to any other product. He did not even have a price data set. He never analyzed rebates or promotion. He never analyzed the *Brown Shoe* factors for defining a market. He never analyzed costs. He never analyzed entry.

Acknowledging their failure of proof on monopoly, Complaint Counsel on appeal argue that the settlement was anticompetitive even if K-Dur 20 was not a monopoly product. But this abandonment of the Bresnahan Test cannot save Complaint Counsel's case. First, Complaint Counsel still cannot satisfy the "reverse payment" requirement. In addition, given the acknowledged procompetitive benefits of patent settlements generally and the unique procompetitive benefits of this particular settlement, this case is governed by the Rule of Reason. But Complaint Counsel did not present the evidence required by the Rule of Reason. Contrary to Rule of Reason requirements, Bresnahan never analyzed the ***net*** competitive effect of the settlement.

Complaint Counsel's case ultimately amounts to an unsubstantiated suspicion. Complaint Counsel theorized a payment for delayed competition. The proof at trial established a *bona fide* side deal for fair value. Complaint Counsel theorized a monopoly. The proof at trial established robust and vibrant competition in a crowded market. Judge Chappell correctly dismissed the claims against Upsher-Smith, and his Initial Decision should be affirmed.

I. SCHERING DID NOT PAY UPSHER-SMITH FOR DELAY

The claims against Upsher-Smith rest on the threshold allegation that certain payments it received from Schering, nominally totaling $60 million, were not *bona fide* royalty payments under a license for Niacor-SR and five other products. (Compl. ¶¶45, 64). In their Trial Brief, Complaint Counsel stated: "This case does not challenge the settlement of patent disputes by an agreement on a date of entry, standing alone, or the payment of fair market value in connection with 'side deals' to such an agreement." (CCTB 43). Bresnahan agreed that a side deal at fair value "would not be anti-competitive," and acknowledged that he does not "have a problem with side agreements." (Bresnahan 932:15-933:4). Further, Bresnahan testified that the determination of fair value is subjective and considered from the time of the transaction: "if Schering-Plough had made a stand-alone determination that it was getting as much in return from those products as it was paying, then I would infer that they were not paying for delay." (Bresnahan 964:23-965:1; *see also* Bresnahan 660:20-661:7, 989:11-990:22).

As Judge Chappell found: "At trial, the evidence established that the June 17, 1997 Agreement between Schering and Upsher-Smith was a type of transaction that Complaint Counsel and their economist concede to be permissible: it was a settlement of a patent dispute by an agreement on a date of entry, with a side deal supported by fair value as determined at that time." (ID 107).

A. The Evidence Establishes That The Niacor-SR License Was A *Bona Fide* Side Deal For Fair Value

Abundant evidence at trial supported Judge Chappell's finding that the $60 million paid by Schering was fair value in connection with a *bona fide* and arms-length licensing transaction. The evidence established that Upsher-Smith had invested millions in the development of its sustained-release niacin product, Niacor-SR, had high expectations for its sales, and had initiated in late 1996 a search for a European licensing partner. For its part, Schering had a documented pre-existing interest in sustained-release niacin. Critically, the Schering executive who evaluated Niacor-SR, James Audibert, did not even know about the patent settlement and performed precisely the type of stand-alone valuation that Bresnahan endorsed. That valuation justified Schering's $60 million royalty payments, and Schering's Board of Directors approved the licensing transaction on that basis. Every element of this powerful proof is supported by contemporaneous business records.

1. Upsher-Smith Invested Millions In Niacor-SR

Unrebutted evidence at trial established that Upsher-Smith devoted unprecedented time, effort and money to develop Niacor-SR. (IDF 181-86). Niacor-SR was Upsher-Smith's "number one research project"; its "crown jewel." (Troup 5474:24, 5431:18). Mark Halvorsen, Upsher-Smith's Director of Clinical and Regulatory Affairs (Halvorsen 3899:9-13), testified that Upsher-Smith spent approximately $13 million on Niacor-SR by the end of the second quarter of 1997 (IDF 185; Halvorsen 3902:13-15; CX 1097 at 153369 (showing $13,582,901 spent by July 1997)). Niacor-SR constituted 80% to 90% of Upsher-Smith's clinical research budget throughout most of the 1990s. (IDF 185; Halvorsen 3902:8-12; Kralovec 5011:1-7; Dritsas 4833:12-16).

2. World-Class Cardiologists And Lipidologists Encouraged Upsher-Smith To Market Niacor-SR

In 1996 Upsher-Smith organized a Niacin Advisory Committee, a blue-ribbon panel of leading cardiologists and lipidologists, to review the clinical data and advise the company on Niacor-SR's prospects. (Halvorsen 3906:9-19, 3925:17-22; Freese 4960:22-4962:3; USX 329 at 113067). Various panel members were authors of leading lipidology studies and had affiliations with the National Cholesterol Education Program, which writes guidelines for physicians who manage cholesterol disorders. *See generally* USX 329; Freese 4964:24-4965:10.

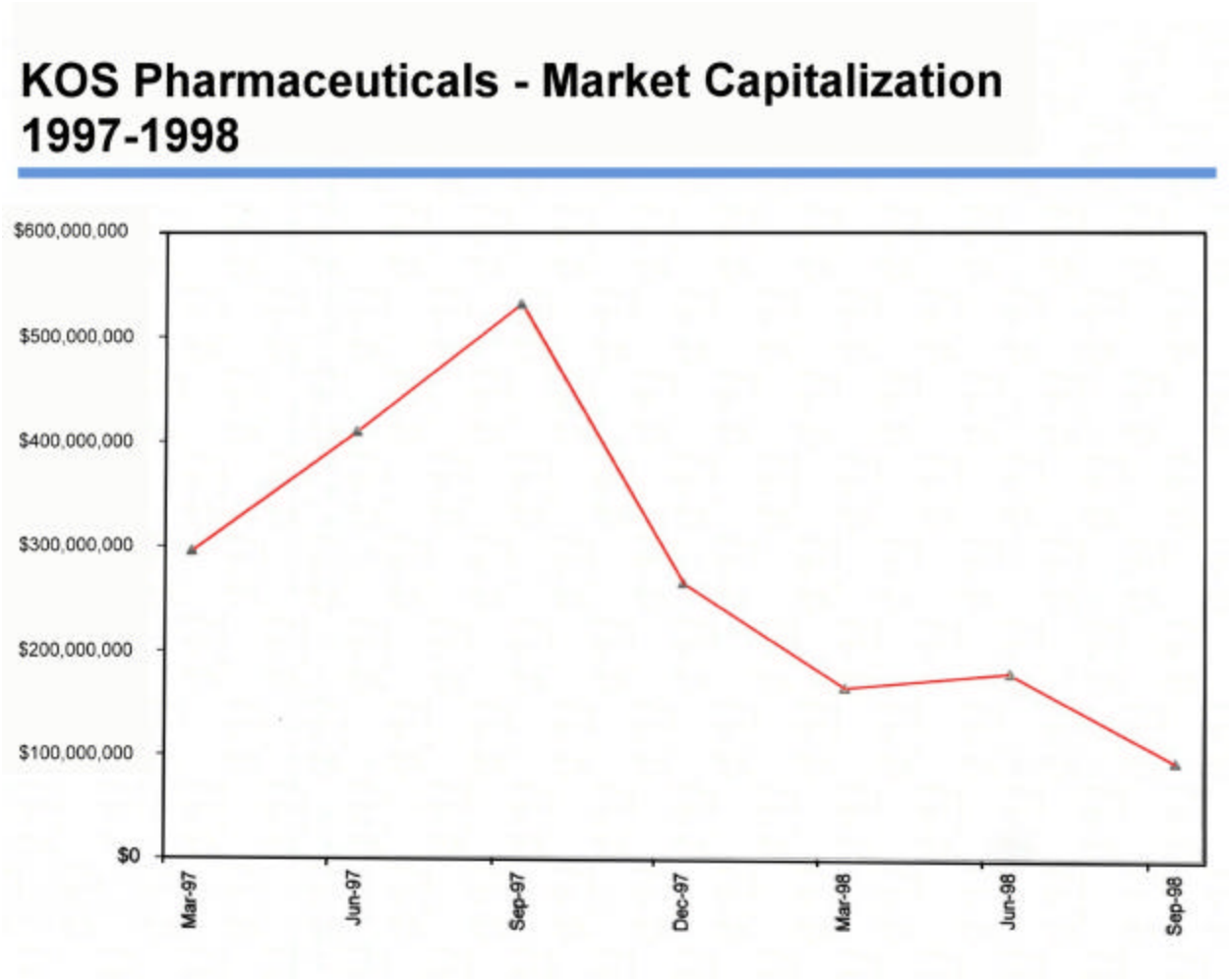
On August 15-16, 1996, the Advisory Committee met with Upsher-Smith representatives in Minnesota. (USX 329 at 113064-65; USX 311 at 111167-70). The trial testimony of Upsher-Smith attendees uniformly established the panel's ringing endorsement of Niacor-SR. (Halvorsen 3928:13-19; Freese 4973:12-16, 4976:5-7). Dr. B. Greg Brown, a member of the Advisory Committee, confirmed that the Committee encouraged Upsher-Smith to develop and market Niacor-SR. (Brown 3171:14-3172:7; 3191:24-3192:8).

3. Upsher-Smith Executives Expected Niacor-SR To Generate Huge Sales

Top Upsher-Smith executives projected annual U.S. sales of Niacor-SR at greater than $100 million per year. (IDF 186). Sales and Marketing VP Dritsas testified that in the first half of 1997 he expected Niacor-SR to achieve annual sales at that level: "I always thought that the product would do at least $100 million, and I was hopeful that it could do $250 million." (Dritsas 4831:14-16). CFO Kralovec testified to an internal projection from the mid-1990s forecasting U.S. sales on the range of $100-$400 million. (Kralovec 5011:23-5012:1; *see* USX 1563 at 10035 (1994 sales projection between $103 million and $414 million by 2000)).

4. Kos Achieved A Market Capitalization Of $400 Million On Expectations For Niaspan

The investment community's independent valuation of Kos Pharmaceuticals in the first half of 1997 bolstered Upsher-Smith's expectations for Niacor-SR. (*See* IDF 187-92). By June 1997, based on Niaspan, Kos achieved a market capitalization of approximately $400 million. (USX 1026; USX 535 at 11515; SPX 225 at 2; USX 21 at 24; *see* USX 1622).



(USX 1030).

Because Niaspan was an extended-release niacin like Niacor-SR, Upsher-Smith management followed Kos's valuation closely. (Kralovec 5025:10-16; Halvorsen 3946:14-25; Troup 5441:21-5443:7). They routinely monitored Kos's stock price (Halvorsen 3946:14-17)

and internally circulated analyst reports on Kos (Kralovec 5023:15-5024:23). As the Initial Decision notes, Upsher-Smith executives perceived Niaspan and Niacor-SR to be "virtually identical." (IDF 188; Halvorsen 3947:23-25). Upsher-Smith considered an analyst's forecast of annual U.S. sales of $250 million for Niaspan to support their own assessment of Niacor-SR. (IDF 191-92; Kralovec 5025:10-5026:5; Troup 5455:5-5456:3; USX 535 at 11515).

5. Upsher-Smith Was Actively Marketing A European License For Niacor-SR At The Time Of The Agreement

To maximize Niacor-SR's potential, in mid-1996 Upsher-Smith began searching for a licensing partner to market Niacor-SR in Europe. (IDF 193-96; USX 155; Kralovec 5016:21-5017:3; Troup 5655:24-5656:8 (*in camera*)). In May 1997, Upsher-Smith began meeting with interested companies and by early June had held face-to-face initial meetings with five different companies. (IDF 196; USX 596-98; CX 800; Halvorsen 3965:7-22; Kralovec 5020:22-5021:19). While still preliminary, Upsher-Smith management was encouraged by the level of interest. (IDF 196; Kralovec 5020:22-5021:3; USX 544 at USL11811).

6. Schering Was Already Interested In An Extended-Release Niacin Product

In early 1997, Schering and KOS extensively discussed co-promoting Niaspan; (Russo 3437:22-3438:10, 3441:7-3442:17; Patel 7511:18-7512:8, 7541:15-25; CX 540; CX 543). Schering viewed a sustained-release niacin as "essential to obtain the early strategic leverage and market expertise that would allow [Schering] to strategically bridge" to ezetimibe — a cholesterol-lowering agent Schering was developing to be a new blockbuster. (SPX 21; Audibert 4108:6-21, 4110:22-4111:8).

Schering executive Ray Russo projected U.S. Niaspan sales at $134 million in 2002, rising thereafter to $193 million. (IDF 213; Russo 3461, 3529; CX 550 at SP 002743). Schering

determined that "the 10 year sales dollar NPV is projected at $420 million." (CX 558). On May 15, 1997, Schering made a serious written proposal to Kos under which Schering would have committed substantial resources to co-promotion. (Patel 7543:3-5).

Kos rejected the proposal in harsh terms that caused Schering to seriously question whether to do a deal with Kos. (SPX 230; *see also* Russo 3465:9-3466:12). The Upsher-Smith opportunity arose shortly thereafter.

7. Schering's James Audibert Valued Niacor-SR Based Upon His Independent Business Judgment

When the Upsher-Smith opportunity arose, Schering's James Audibert undertook a commercial assessment of Niacor-SR. (Audibert 4112:4-19). Audibert was a 22-year veteran of Schering/Key, with extensive experience in cholesterol-reducing drugs and extended-release formulations. *See* IDF 228-37. Audibert had been personally involved in Schering's Kos discussions for Niaspan. *See* IDF 238-42; Audibert 4100:17-4103:10.

Audibert was unaware that the Niacor-SR licensing opportunity had arisen in the context of a patent settlement. (ID at 108; Audibert 4113:8-11). Audibert also was unaware of the "amount of money that was being asked for the license rights by Upsher." (ID 108; Audibert 4113:8-11). Thus, his business judgment could not have been influenced by the settlement.

Audibert projected in his commercial assessment: "Niacor SR is expected to be launched in early 1999 with 3rd-year sales of $114 million." (ID 108; SPX 2 at SP 16 00045). He added that Niacor-SR could generate annual sales of $149 million by 2008. (ID 108; Audibert 4127:17-4128:4; SPX 2).

Audibert's sales projections represented his best business judgment as to Niacor-SR's value. (Audibert 4129:1-13, 4225:19-4226:5; SPX 2). Schering performed its standard calculation of the economic value of this transaction based on Audibert's analysis and confirmed

that "Niacor-SR presented an economic value to Schering of between $225-265 million . . . ." (SPX 26 at 16 00275; IDF 259).

The other five pharmaceutical products that Upsher-Smith licensed to Schering also had value. (*See* ID 108; IDF 165, 197-200). According to the Schering's Board Presentation, Schering forecasted sales of Prevalite, Klor-Con 8, 10 and M20 and Pentoxifylline "to be $8 million a year in the first full year of launch, growing to $12 million a year in the second full year" with expected net margins of "between 35% and 50%." (CX 338 at SP 12 00271).

8. Audibert's Valuation Was Reasonable

At trial, various experts independently supported the reasonableness of Audibert's valuation of Niacor-SR. Zola Horovitz, a longtime licensing executive at the Squibb Institute, determined that Audibert's sales projections justified an up-front payment of up to $100 million. (IDF 260; Horovitz 3607:2-3613:11, 3618:3-18). Before making this determination, Horovitz was not told how much Schering actually paid. (Horovitz 3618:19-23). Horovitz also testified that Audibert's assumptions were reasonable. (Horovitz 3667:3-3675:21). European-pricing expert James Furniss also testified that Audibert's pricing assumption was reasonable. (Furniss 4239:1-5). Similarly, economist Dr. William Kerr did his own NPV analysis and determined that Niacor-SR was worth well more than $60 million to Schering. (Kerr 6289:5-23).

Kerr also conducted an independent NPV analysis of the five other licensed products. Using a five-year time horizon, he placed their value at $10.1 million as of June of 1997. (UPF 458; Kerr 6301:4-6302:6). When Kerr used a ten-year time horizon, that figure approached $17 million. (Kerr 6312:3-12).

B. Complaint Counsel's Nelson L. Levy Provided Unsubstantiated Opinions

Complaint Counsel proffered Levy as an expert "in the field of pharmaceutical licensing and pharmaceutical valuation." (Levy 1304:2-6). At trial, however, Levy proved to be unqualified and unprepared to provide reliable opinions on Niacor-SR's value. Judge Chappell, in twenty-eight separate findings of fact, assiduously set out the basis for his determination that "Dr. Levy's testimony is contradicted by the greater weight of the evidence." (ID 109; *see* IDF 290-318).

1. Levy Did Not Perform Any Valuation Of Niacor-SR Or The Other Products Licensed

Although proffered as a valuation expert, Levy never performed a net-present-value ("NPV") analysis for Niacor-SR. (IDF 290).[1] He never undertook ***any*** quantitative valuation of Niacor-SR or any of the other products Upsher-Smith licensed to Schering. Levy conceded on cross:

Q: Klor Con 8.

A: Klor Con 8?

Q: Yes, Sir, you didn't do an NPV analysis on Niacor-SR, correct?

A: That's correct.

Q: And sir, you didn't do an NPV analysis on Klor Con 8, correct?

A: On what, I'm sorry?

Q: Klor Con 8.

A: I am drawing a blank on Klor Con 8.

[1] Bresnahan conceded that the three royalty payments had a net-present-value in June 1997 of $54.5 million. (Bresnahan 6298:24-6299:3). Levy, however, incorrectly based his opinions on whether Niacor-SR was worth an undiscounted $60 million in 1997. (Levy 2057:25-2058:2; 2059:13-16).

Q: You don't remember doing an NPV analysis on Klor Con 8, do you?

A: No, I don't.

Q: Do you remember doing an NPV analysis on Klor Con 10?

A: No, I didn't do one on Klor Con 10 either.

* * *

Q: And you didn't do an NPV analysis on Klor Con M20, did you?

A: No.

Q: And you didn't do an NPV analysis on pentoxifylline, did you?

A: Pentoxifylline, no.

Q: And you didn't do an NPV analysis on Prevalite, did you?

A: No.

Q: In fact, you didn't use any valuation methodology on any of those products, did you?

A: I don't think it was part of my — the area of expertise that I was asked to opine upon to do valuations, to do financial valuations on any of these products.

* * *

Q: Sir, you didn't do any quantitative analysis of the value of any of those products, did you?

A: That's correct.

(Levy 2057:25-2058:14, 2059:2-16, 2064:23-25). Levy's rejection of NPV analysis (or any other valuation methodology) is out of step with every other trial witness and industry practice. (IDF 291-92).

Levy's unsupported opinion was even deficient on its face. His conclusory opinion addressed only whether Niacor-SR was worth $60 million. (Levy 1307:4-11). But Bresnahan testified that the determination of "net positive value" under the Bresnahan Test had to be

determined as of June 1997 (Bresnahan 659:21-661:7), and that as of then the NPV of Schering's upfront royalty payments was $54.5 million, not $60 million (Bresnahan 661:14-664:6).

2. Levy Did Not Consider Kos's Market Value

In reaching his conclusions as to the value of Niacor-SR, Levy failed to consider the value the public markets placed upon Kos's Niaspan. (ID 109). Levy admitted as much:

> **Q:** In performing your analysis in connection with this case, did you consider the fortunes of the Kos stock price?
>
> **A:** No.

(Levy 2076:12-15). Levy was forced to concede that Kos's market capitalization on June 17, 1997 was "in the neighborhood of $400 million" on the strength of Niaspan. (Levy 2074:16-2075:6).

3. Levy Did Not Consider The Production Rights Accorded Schering

Levy made no attempt to value the production rights accorded to Schering under the Agreement. (IDF 294). He never considered them:

> **Q:** Sir, did you do any valuation analysis on the production rights that were given to Schering-Plough by Upsher-Smith in the June 17, 1997 licensing agreement?
>
> **A:** I'm sorry, the production rights?
>
> **Q:** Yes.
>
> **A:** I'm not sure what you're referring to, sir.
>
> * * *
>
> **Q:** Are you aware of any production rights or supply rights that Schering-Plough got in that June 17, 1997 agreement?
>
> **A:** I don't recall those.
>
> **Q:** In forming your opinions in this case, did you take into account any production rights or supply rights provided by Upsher-Smith to Schering-Plough in that agreement?

A: No.

(Levy 2059:21-2060:20).

4. Levy Was Not Qualified To Assess Niacor-SR

Levy was plainly outside his expertise in opining on niacin and industry knowledge about niacin in 1997. This absence of the expertise required under *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), was the basis of Upsher-Smith's motion in limine to exclude his testimony. Judge Chappell's denial of the motion reflected an abundance of caution, but at trial it was plain the testimony did not meet the *Daubert/Kumho* requirements. Judge Chappell accorded Levy's testimony less weight because "his opinions regarding the value of Niacor-SR are founded in part on his conclusions regarding the safety and efficacy of Niacor-SR and his testimony demonstrated he lacked expertise in the area of cholesterol-lowering drugs and niacin." (ID 109).

Levy acknowledged that he is not a cardiologist, lipidologist, or toxicologist. (Levy 8409:4-11). He has not practiced medicine in twenty years ("I've never practiced medicine in the true sense of the word"), and even then, did not specialize in cholesterol management. (Levy 8410:2-8411:2). Levy failed to recognize the names of the world-class cardiologists and lipidologists who served on Upsher-Smith's blue ribbon panel (Levy 8406:14-20); he was unfamiliar with the leading lipidology studies (IDF 308; Levy 8401:2-8404:2); and he was not familiar the National Cholesterol Education Program ("NCEP"), even though it promulgates national cholesterol guidelines and is referenced throughout the record — including one of his main exhibits, CX 1042. (Levy 1371:9-24; IDF 308; *see, e.g.,* Halverson 3931:22-3932:6; Audibert 4099:11-24; USX 308). These failures reflected both a general lack of familiarity with the cholesterol field and a specific lack of familiarity with the record.

5. Levy's Review Of Post-Deal Conduct Was Flawed

Levy opined that the post-deal conduct of Schering and Upsher-Smith was inconsistent with a *bona fide* intention to develop Niacor-SR, but this opinion was based on factual misunderstandings, an unfamiliarity with post-deal communications and the concomitant and dramatic failure of Kos's Niaspan. Judge Chappell ruled that Levy's opinion was "rebutted by the evidence Respondents presented on their post-deal conduct and discredited because Levy did not review many of the documents reflecting the parties' communications and continued work on the licensed products." (ID 109; IDF 315-18).

Levy was also uninformed as to the larger picture, the dramatic market crash of Kos in late 1997. He was unaware that on November 12, on the news of the unexpectedly poor sales, Kos stock plummeted to $16.56, losing 46% of its value. (USX 1027; USX 1028). This was a major disincentive to Upsher-Smith's development of Niacor-SR, and caused management to suspend Niacor-SR approval efforts. (Troup 5480:20-5481:6; Halvorsen 3989:9-14). Noting Kos's failure, Schering later made a similar decision to forego its European Niacor-SR approval effort. (CX 1111). Inexplicably, Levy did not take Kos's fortunes into account. (Levy 2076:12-15).

C. Complaint Counsel's Timothy F. Bresnahan Provided Unsubstantiated Opinions

Professor Bresnahan was the only other Complaint Counsel witness purporting to support the "payment for delay" allegation. Like Levy, he provided purely opinion testimony. And like Levy, his opinions were demonstrably unfounded.

1. Bresnahan Never Valued The Products Or Production Rights

Bresnahan never attempted to value the rights Schering obtained under the licensing agreement: "I haven't done a valuation analysis." (IDF 319; Bresnahan 949:18-25). But Bresnahan admitted that he ***could*** have done a valuation:

> **Q:** And you testified at your deposition that economists do have economic valuation tools where they can take a look at a stream of potential payments, discount those payments and come up with a present value, can they not?
>
> **A:** Yes.
>
> **Q:** But you haven't done that for the Niacor-SR and the license contained in this agreement?
>
> **A:** That's correct.

(Bresnahan 950:1-9). Beyond Niacor-SR, Bresnahan admitted that he never valued of any of the products licensed to Schering or the production rights associated with those licenses. (IDF 319; Bresnahan 950:1-957:19). Yet he admitted that each of the six products and each of the six production rights had positive economic value. (IDF 293; Bresnahan 950:1-957:19).

As Judge Chappell observed: "Professor Bresnahan also did not challenge the Niacor-SR sales projections, estimated cost of goods sold, net profit, or the economic value of $225-$265 million presented to Schering's Board of Directors." (IDF 319; Bresnahan 975:7-978:6; CX 338).

2. Bresnahan Misapplied His Revealed Preference Test

In lieu of any alternative valuation, Bresnahan relied on his "revealed preference" test. (Bresnahan 578:14-598:8). But his work betrays a fundamental misunderstanding of the factual record. (*See* IDF 320-21). According to Bresnahan, Schering's "turning down" of Kos's Niaspan "revealed" that Schering was not willing to pay for the comparable Niacor-SR product.

(Bresnahan 580:1-598:8). From this "revelation," Professor Bresnahan deduced that Schering's royalty payments were compensation for something other than Niacor-SR.

In fact, as set forth above, Schering demonstrated a genuine interest in Kos's sustained-release niacin product, projected substantial sales for that product, engaged in an extended dialogue with Kos, and made a serious offer incorporating a major financial commitment commensurate with the proposed copromotion's profit split. (IDF 321). Kos rejected Schering; not the other way around. A further offer by Schering was foreclosed only by Kos's aggressive demands and contentious tone. "The substantial reliable evidence demonstrates legitimate credible reasons for Schering's preference of a licensing deal with Upsher-Smith over a co-marketing arrangement with Kos. F. 217-19." (ID 110). Fair consideration of Schering's negotiations with Kos actually "reveals" that well before the Niacor-SR opportunity arose, Schering had a substantial interest in sustained-release niacin and a *bona fide* belief that such a product could be profitable and strategically important to Schering's business. (*See* IDF 321-22).

3. Bresnahan Misapplied His Market Test

Bresnahan also relied on a "market test," but he misapplied that test as well. (Bresnahan 598:9-607:4). Bresnahan reviewed Upsher-Smith's search for a licensing partner for Niacor-SR in Europe and, seeing no offer of a substantial non-contingent payment, concluded that "the market wasn't willing to come up with a large noncontingent payment for this opportunity." (Bresnahan 599:10-19, 602:4-9). Bresnahan was not qualified to give this opinion, and it is unsound.

Bresnahan has no experience valuing pharmaceutical products, valuing pharmaceutical licensing opportunities, or even reviewing licensing efforts by pharmaceutical companies. (Bresnahan 1280:16-19, 1125:5-25). "Professor Bresnahan had never before applied this market

test in the context of pharmaceutical licensing, and he did not understand, when he applied it, how Schering normally goes about deciding what to pay for a license." (IDF 324). Bresnahan was unaware that while certain companies may lack interest in a product, other companies may place great value on it. Complaint Counsel's fact witness, James Egan, a former Searle licensing executive, testified that one company may value a licensing opportunity differently from another:

> **Q:** Sir, some people may value a licensing opportunity different from others, correct?
>
> **A:** That's right.
>
> **Q:** In part, differences can be attributed to subjective criteria, correct?
>
> **A:** Yes.
>
> **Q:** Or to a company's specific commercial needs, correct?
>
> **A:** Yes.
>
> **Q:** Now, sir, in your career, there have been occasions where you passed on a licensing opportunity that another company then accepted, correct?
>
> **A:** Yes.
>
> **Q:** And there may have been occasions where others have passed on a licensing opportunity that you then accepted, correct?
>
> **A:** Yes.
>
> **Q:** In fact, sometimes, sir, a lot of people turn down a licensing opportunity, but then the product in question goes on to be a success for someone else, correct?
>
> **A:** That's right.

(Egan 7964-65; *see* IDF 324).

Upsher-Smith's marketing of a Niacor-SR license was in full swing as of June 17, 1997. Upsher-Smith was in active discussions with a variety of companies. (Bresnahan 1035:10-1039:22; Kerr 6317:18-6324:16). Upsher-Smith held confidential meetings with five different potential licensees in the three weeks preceding June 17, 1997. (Egan 7876; USX 586; USX

597; USX 598; CX 880). Those companies indicated they would review Niacor-SR and contact Upsher-Smith, but not within the following month. (IDF 325). No conclusions as to Niacor-SR's value could possibly be drawn from this ongoing process. Because Upsher-Smith terminated its marketing effort after signing the exclusive Agreement on June 17, 1997, one can never know what the results would have been had Upsher-Smith not reached a deal with Schering.

Oddly, Bresnahan ignored the best "market test" available. While he acknowledged that Kos's Niaspan was "comparable" to Upsher-Smith's Niacor-SR (Bresnahan 596:13-20; 1015:19-22), he did not consider Kos's $400 million market capitalization as of June 17, 1997 (Bresnahan 1128:14-1129:24). (*See* USX 1608). The parties discussed this "market test" when they were negotiating the price of the licenses. (Cannella 3829:22-3830:10; Troup 5441:22-5443:17). The Initial Decision concludes that the evidence "refutes the conclusion Bresnahan reached using his market test." (ID 110).

4. <u>Bresnahan Misplaced Reliance On "Incentives"</u>

Bresnahan relied on the "incentives" of Schering and Upsher-Smith to engage in a transaction exchanging a payment for delay. (Bresnahan 527:2-534:19). But this "incentive" could not be particularly strong, for Bresnahan conceded: "[T]he risk in the litigation did not put Schering, the corporation, or especially not its shareholders at any — at any great risk, because the K-Dur product line is small relative to the total shares of — I'm sorry, to the total sales of the Firm . . . ." (Bresnahan 8075:24-8076:5). Bresnahan opined that K-Dur's contribution to Schering's total sales was "so small as to be ignorable in terms of its profit contribution." (Bresnahan 8187:22-8189:8).

Furthermore, Bresnahan ignored countervailing "incentives," such as the incentive to comply with the antitrust laws. And Bresnahan ignored substantial evidence that the parties

were determined to avoid a payment for delay. (John Hoffman 3543:11-3544:13; Cannella 3825:11-22; CX 338 at SP 12 00268 ("any such deal should stand on its own merit.")).

Ultimately, Professor Bresnahan was compelled to admit that theoretical "incentives" hardly constitute evidence of actual improper conduct:

> **Q:** Professor, is it your view that if a person has an economic incentive to violate the law, that that leads to the conclusion that they did so?
>
> **A:** No.

(ID 110 (quoting Bresnahan 1105:22-5)). The law agrees. *See, e.g.*, *Serfecz v. Jewel Food Stores*, 67 F.3d 591, 600-601 (7th Cir. 1995) (holding that "the presence of an economic motive is of very little probative value" and that "[t]he mere existence of mutual economic advantage, by itself, . . . supplies no basis for inferring a conspiracy"). The Initial Decision aptly noted that Bresnahan's "theory" was contrary to Respondents' direct evidence that "the parties did not exchange money for delay. F. 322-26." (ID 110).

Another fundamental concession by Bresnahan justifies Judge Chappell's finding. As noted above, Bresnahan testified that he would infer ***no*** payment for delay "if Schering-Plough had made a stand-alone determination that it was getting as much in return from those products as it was paying." (Bresnahan 964:16-965:11). As also noted, Bresnahan described his valuation test as a subjective one. (Bresnahan 965:12-966:2). The fact testimony established that Schering — and Audibert in particular — ***did*** make a "stand-alone determination that it was getting as much in return from those products as it was paying." Thus, there was no payment for delay even under Bresnahan's own test.

D. The Parties' Negotiations And The June 1997 Agreement Itself Confirm That There Was No Payment For Delay

The evidence of the Respondents' negotiations — testimony and contemporaneous documents — as well as the Agreement itself confirm that Schering did not pay Upsher-Smith for delay. Complaint Counsel's discussion of this evidence is incomplete and misleading.

1. The Negotiations Show That Schering Would Not Pay For Delay

Complaint Counsel emphasize that, in negotiations with Schering, Troup asked whether Schering would be paying money in connection with the settlement. (CAB:26-27). But Complaint Counsel ignore the uncontroverted testimony of all of the negotiators that Schering emphatically rejected the idea, and that the parties moved on to settle by splitting the remaining patent life and only then negotiated a side deal for fair value. (UPF 505-94).

Complaint Counsel take great liberties with the negotiation evidence. For example, Complaint Counsel assert that the record is "clear and consistent" that Troup "repeatedly asked Schering to 'pay Upsher-Smith to stay off the market,'" citing the deposition of Schering's John Hoffman. (CAB:26). In fact, Hoffman's cited deposition testimony was: "[D]uring the meeting in Kenilworth, I recall something being said that I took — maybe I thought might be an invitation to pay Upsher-Smith to stay off the market. I said that that was not something we were going to do, and I didn't think it was a discussion we should have, and Mr. Cannella [Upsher-Smith's outside counsel] agreed with me, and that was the end of the subject." (CX 1509 at 33:15-22).

Similarly, Complaint Counsel provide a quote from Troup's investigational hearing in which Troup acknowledged asking Schering whether Upsher-Smith would be compensated for its "theoretical lost revenue." (CAB:26). But Complaint Counsel neglect to mention that Troup,

in the very same passage, gave Schering's response to his question: "They said absolutely not at all . . . ." (CX 1529 at 112:3).[2]

Indeed, the record testimony from all of the participants in the negotiations is "clear and consistent" that the parties did ***not*** exchange money for delay. (Troup 5422:20-25, 5460:11-22; Cannella 3851:6-10; John Hoffman 3544:4-13). The testimony of these witnesses is also "clear and consistent" that Schering's monetary obligations under the licensing agreement were compensation for Niacor-SR and the other products being licensed by Upsher-Smith. (Cannella 3855:12-17; John Hoffman 3573:3-7; Troup 5499:14-5500:5).

The only inference that could be drawn from the negotiators' testimony is that Schering's representatives were acutely sensitive to antitrust concerns and aggressively committed to antitrust compliance. When Troup made even a vague comment about Upsher-Smith's cash needs, Schering immediately and forcefully declared that it would not compensate Upsher-Smith for delay. (UR-CPF 200 ¶3). *See In re Citric Acid Litig.*, 191 F.3d 1090, 1098 (9th Cir. 1999) (holding that "it would ***not*** be reasonable to infer that" defendants conspired to fix prices "merely from evidence that an illegal course of conduct was suggested but immediately rejected") (emphasis added).

As Judge Chappell found, the evidence established that Upsher-Smith and Schering agreed on the September 1, 2001 entry date before they agreed to the licensing agreement's

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[2] In discussing what Troup said during the negotiations, Complaint Counsel rely heavily on Part II Investigational Hearings ("IHs") of Schering executives. Upsher-Smith and its counsel never had notice of these pre-Complaint IHs, nor had any right to attend or participate. Judge Chappell properly ruled that these IHs were not admissible evidence against Upsher-Smith. (PHC 297-98; Order dated April 9, 2002). Upsher-Smith expressly reserves its objection to the use of any IHs against it, for the reasons stated in Upsher-Smith's Motion in Limine of January 3, 2002. In any event, these IHs are consistent with the deposition and trial testimony that Schering categorically rejected the concept of paying Upsher-Smith any money in connection with the settlement.

financial terms. (IDF 137; Troup 5430:1-13, 5428:5-23; CX 1488 at 64:18-65:3; SPX 1263 at 65:5-6, 12-15 (Cannella Dep.)). This fact was vividly established at trial by Nicholas Cannella, Upsher-Smith's outside counsel, who testified that when he entered the negotiations on June 12, 1997, the entry date had been set and was not negotiated thereafter. (Cannella 3838:19-3839:7).

The record is devoid of any evidence that the parties ever considered any entry date earlier than September 1, 2001. (*See* IDF 137 ("Schering never suggested that it would consider an entry date earlier than September 1, 2001.")). In fact, the evidence indicates that Schering initially proposed a date as late as 2006, only to be negotiated down by Mr. Troup to a virtually Solomonic splitting of the patent life. (Troup 5425:16-5426:6).

The record is also clear that when the parties turned to negotiate the consideration Schering would pay for the licenses, the negotiations focused on appropriate financial considerations such as: Niacor-SR's market potential (IDF 145; Troup 3868:3-11, 5441:22-5443:7); Kos's market value (IDF 145; Troup 5442:2-5443:7, 5583:16-5587:21; Cannella 3829:13-3830:10; CX 1509 at 17:20-25 (John Hoffman Dep.)), and the size of the worldwide cholesterol-fighting market (IDF 152; Troup 5453:13-23). Upsher-Smith's licensing consultant, Andrew Hirschberg, advised Troup to request $100 million for the Niacor-SR license. (Troup 5448:7-18). Troup in fact requested $80 million (IDF 146; Troup 5448:25-5449:12; John Hoffman 3544:14-3545:20; Cannella 3829:13-3830:10), and Schering negotiated him down to the consideration in the June 1997 Agreement for Niacor-SR and the other products and associated production rights — staggered payments of $28 million, $20 million and $12 million (a value of $54.5 million as of June 17, 1997), with milestones and running royalties (IDF 152; Troup 5453:13-23, 5454:7-5455).

2. Contemporaneous Documents Corroborate The Negotiators' Testimony

The Schering Board Presentation (CX 338), a contemporaneous business record, corroborates the testimony of the negotiators. Complaint Counsel misplace reliance upon the Presentation's statement that Upsher-Smith was seeking "a guaranteed income stream for the next twenty-four months to make up for the income that they had projected to earn from the sales of Klor-Con had they been successful in their suit." (CAB:27 (quoting CX 338 at SP 1200270)). This statement does not indicate that Schering's license fees were more than fair value; it merely reports Upsher-Smith's stated motivation to do the licensing deal (i.e., to replace their theoretical revenues if they had won the uncertain litigation). Furthermore, Complaint Counsel ignore that the Presentation reports Schering's response to Upsher-Smith: "we informed them that any such deal should stand on its own merit independent of the settlement." (CX 338 at 12 00268). The Presentation thus provides dead-on corroboration of the negotiators' testimony.

After reporting Schering's requirement that the licensing deal "stand on its own merit," the Presentation goes on to analyze the deal's independent merit. It contains a narrative overview of Niacor-SR, explaining the size of the non-NAFTA cholesterol-lowering market ($4 billion in 1996 and projected at $15 billion in 2008) (CX 338 at 12 00269), the competitive landscape, the attributes and challenges of niacin therapy, the clinical data for Niacor-SR, and the projected sales for Niacor-SR. (CX 338 at 12 0068-71). A table accompanying the Board Presentation projects Niacor-SR sales eventually rising to $149 million. (CX 338 at 12 00273). Another table calculates an economic value of $225-$265 million, providing a 43% internal rate of return. (CX 338 at 12 00275).

The Board Presentation also describes the other products included in the license, projecting annual sales of these products peaking at $12 million in the second full year, with net

margins of between 35% and 50%. (CX 338 at 12 00271). The Presentation notes that these licenses are royalty-free, and briefly summarizes the strategic justification for these products. (CX 338 at 12 0027-72). The Presentation also discusses Upsher-Smith's obligation to source all of the products at cost (except for U.S. sales of Prevalite, which is cost plus 30%). (CX 338 at 12 00271).

All told, the Schering Board Presentation is a business-like analysis of the licensing opportunity available to Schering. In no way, shape or form does the Presentation suggest that Schering would be paying more than fair value for the licenses. Nor does it suggest that Schering was paying Upsher-Smith "for keeping its generic K-Dur 20 product off the market," as Complaint Counsel contend. (CAB:27).

Complaint Counsel also misplace reliance upon an "Executive Summary" from Schering's files, {

}. (CX 283 (*in camera*)). First, and foremost, {

}. (CX 283 at 018780 (*in camera*)). Second, while Complaint Counsel focus upon {

}. (CX 283 at 018780 (*in camera*) (emphasis supplied)). This {

}, accords with what Complaint Counsel concede is a lawful side deal.

3. The June 1997 Agreement Itself Confirms No Payment For Delay

Complaint Counsel next argue that the terms of the June 1997 Agreement establish a payment for delay. (CAB:29-30). This interpretation is untenable and Judge Chappell was right to reject it.

a. Under Paragraph 11 SP Licensee Is Expressly Paying "Royalties"On Product Licenses

The June 1997 Agreement (CX 348) reflects the parties' intention that they simultaneously settle the litigation and enter into a side deal supported by its own terms. The opening sentences of the Agreement indicate that the parties distinguished between the settlement and the licensing transaction: "This will serve as our Agreement as to the terms under which [the parties] will settle the above action and will enter into a transaction licensing rights to certain Upsher-Smith products to an affiliate of Schering." The ensuing sentences likewise distinguish between "the settlement," on the one hand, and "the licensing transaction" or "the license grants," on the other hand.

Paragraph 11 of the Agreement expressly describes the $28 million, $20 million and $12 million payments as "upfront royalty payment[s]." (CX 348 at 03188). The term "royalty" unmistakably signifies that the payments were for the product licenses. (ID 111); *see, e.g.*, *Sierra Club, Inc. v. Commissioner*, 86 F.3d 1526, 1531 (9th Cir. 1996) (noting that "'royalty' commonly refers to a payment made to the owner of property for permitting another to use the property") (citing *Black's Law Dictionary* 1330-31 (6th ed. 1979)); *see also* DENNIS W. CARLTON AND JEFFREY M. PERLOFF, MODERN INDUSTRIAL ORGANIZATION 528 (3d ed. 2000) ("The patent holder may produce the product (or use its new process) or ***license*** (permit) others to produce it in exchange for a payment called a ***royalty***.") (emphasis in original).

Furthermore, in Paragraph 11 the designated payor of the "royalty" payments is "SP Licensee," which is defined in Paragraph 7 as the recipient of the license rights and used in Paragraphs 7-12 and 18 exclusively. In specifying that "SP Licensee" is making the "royalty" payments, Paragraph 11 plainly indicates that the payments are for the licenses Upsher-Smith was conveying to "SP Licensee."

Under New Jersey law, which expressly governs the June 1997 Agreement (CX 348 at 03184 (¶IV)), the circumstances surrounding the formation of the contract and the parties' intentions must also be considered. As the New Jersey Supreme Court stated in *Atlantic N. Airlines, Inc. v. Schwimmer*, 96 A.2d 652 (N.J. 1953):

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

96 A.2d at 656 (emphasis supplied). Here, the attendant circumstances confirm that the parties intended that Schering (i.e., SP Licensee) pay Upsher-Smith for the product licenses and supply rights.

Negotiators from Upsher-Smith (including its outside counsel) and Schering testified uniformly that the royalty payments under Paragraph 11 were discussed in the negotiations solely as compensation for the licenses from Upsher-Smith to Schering. (Troup 5472:16-5473:6, 5555:18-5556:19; Cannella 3854:22-3855:19; John Hoffman 3564:22-3565:2).[3]

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[3] This testimony flatly dispels the incorrect suggestion by Complaint Counsel that Mr. Troup tried to reconcile some perceived tension between his testimony and the terms of the Agreement. (CAB:1-2, 30). To the contrary, Mr. Troup commented that ***Complaint Counsel's interpretation of the Agreement's provisions***, which omitted any reference to the SP Licensee language, incorrectly stated what the negotiators understood "notwithstanding … a typo or someone missed something" in drafting Paragraph 11. (Troup 5555:25-5565:13). Contrary to

(. . . continued)

Schering's Board Presentation corroborates this testimony. It presents the licensing transaction as a deal "stand[ing] on its own merit." (CX 338 at 12 00268). The Presentation does not even refer to the entry date under the patent settlement. Instead, it provides a financial justification for the licensing transaction based strictly on the transaction's own merit. As Complaint Counsel acknowledge, such a contemporaneous document is highly probative. (CAB:20).

In the face of this overwhelming evidence that Schering was paying for the product licenses, Complaint Counsel misplace reliance on Paragraph 11's prefatory language: "In consideration for the licenses, rights and obligations described in paragraphs 1 through 10 above, . . ." But this prefatory language merely recites, in boilerplate fashion, that the payment obligations of "SP Licensee" are supported by legal consideration. Such a recitation is, of course, a common and prudent device to avoid having an agreement rendered unenforceable for failure of consideration. The language does not indicate or suggest that the amount of the payment obligations is affected by the terms of all of the referenced paragraphs.[4]

Nothing about the prefatory language suggests that SP Licensee was agreeing to pay more than fair value in "upfront royalty payment[s]," "milestone payments" or running "royalties" in exchange for a later entry date. Any such suggestion is refuted not only by the

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(continued . . .)

Complaint Counsel's assertions, the Initial Decision nowhere relies on this portion of Troup's testimony.

[4] In quoting selectively from John Hoffman's testimony, Complaint Counsel attempt to foster the impression that Hoffman did not dispute their interpretation of Paragraph 11. (CAB:13 & n.8). In fact, Hoffman acknowledged the prefatory language of Paragraph 11 but expressly disputed Complaint Counsel's interpretation. He testified that the notion Schering's payments were in any part for the patent settlement was "directly contrary to every discussion we had had." (John Hoffman 3565:3-10).

plain language of the Agreement but also by the extrinsic evidence of the parties' intentions, which are necessarily considered under New Jersey law.

b. SP Licensee's Payment Obligation Hinged On The Validity Of The Product Licenses And Upsher-Smith's Performance

Contrary to Complaint Counsel's suggestion (CAB:30-31), no provision in the June 1997 Agreement links SP Licensee's payment obligation to Upsher-Smith's generic-entry date. Indeed, Paragraph 12 of the Agreement confirms that the royalty payments were compensation for the licenses of Niacor-SR and the other products, and nothing else. Under Paragraph 12, if the product licenses provided to SP Licensee are ruled void or invalid, then the obligation to make royalty payments terminates. Notably, Paragraph 12, the only paragraph that addresses the early termination of the SP Licensee payment obligation, does not state that the obligation to make royalty payments hinges on Upsher-Smith's right to introduce its generic product on September 1, 2001. Paragraph 12 does not even contain any reference to Paragraph 3, which addresses Upsher-Smith's right to enter prior to September 2001.

Complaint Counsel even attempt to draw some nefarious inference from a standard *force majeure* clause. (CAB:31). That clause, which actually appears twice in the June 1997 Agreement (CX 348 at 03184-85, 03193), was not discussed in the negotiations between Schering and Upsher-Smith. (Cannella 3858:1-3859:25). The clause appears to be Schering's boilerplate provision. (Cannella 3859:19-3859:25). Complaint Counsel argue that the clause somehow shows a payment for delay, but that argument is based on a misreading of the provision.

The *force majeure* clause in the Agreement excuses a failure to perform when acts of God or other specified extraordinary circumstances intervene. This provision, which is simply an allocation of risk, is customary in all respects. *See, e.g., Gulf Oil Corp. v. FERC*, 706 F.2d

444, 448 (3d Cir. 1983) (addressing a substantially identical *force majeure* clause). Complaint Counsel evidently read this provision to mean that Schering (i.e., SP Licensee) would have had to pay Upsher-Smith the $60 million in upfront royalty payments even if an act of God prevented Upsher-Smith from delivering the licenses or manufacturing the licensed products. This interpretation is flawed. While the *force majeure* clause under these circumstances would save Upsher-Smith from liability or breach, Upsher-Smith would not be entitled to payment from Schering. *See, e.g.*, 14 CORBIN ON CONTRACTS § 78.7 (2001) ("A seller who has promised to deliver specific goods may be discharged by their destruction without fault, yet if the seller has received part or all of the price from the buyer, the seller must make full restitution to the buyer."). The *force majeure* clause effectively suspends the obligations of both parties until performance can be resumed. *Wartsila Diesel, Inc. v. Sierra Rutile, Ltd.*, No. CIV. A. 95-2958, 1996 WL 724929 at * 11 (E.D. Pa. Dec. 16, 1996). Thus, the last sentence of the clause refers to the parties negotiating a "mutually satisfactory resolution to the problem, if practicable."

More fundamentally, whether Schering would have had to make the upfront royalty payments upon the occurrence of a hypothetical act of God has no bearing on whether those royalty payments were for the product licenses or for delay. In addition, the *force majeure* clause does not link the upfront royalty payments to Upsher-Smith's entry date under the settlement.

Furthermore, Upsher-Smith was not free from obligations to Schering, as Complaint Counsel suggest. Under New Jersey law, Upsher-Smith was obligated to cooperate reasonably with Schering to allow Schering to exploit the licenses. *See Association Group Life, Inc. v. Catholic War Veterans*, 293 A.2d 382, 384 (N.J. 1972) (stating that the requirement of good faith and fair dealing means that "neither party shall do anything which will have the effect of

destroying or injuring the right of the other party to receive the fruits of the contract") (internal quotations omitted). (*See also* USX 1542 at 66:5-13, 68:13-4, 71:20-72:5 (Wasserstein Dep.)). Upsher-Smith was also expressly obligated to provide the six products to Schering, and except in the case of Prevalite sales for the United States, at cost. The Schering Board presentation noted this obligation repeatedly. (CX 338 at SP 12 00271). Troup described this as an "onerous obligation," (Troup 5461:14-20), and Kralovec was concerned that the supply agreement for the six licensed drugs would consume Upsher-Smith's capacity and compromise existing production, (Kralovec 5031:4-5032:7). Furthermore, in successfully negotiating to have the $60 million in upfront royalty payments staggered over two years, Schering not only reduced the value of those payments but also retained leverage to assure Upsher-Smith's reasonable cooperation. (USX 1542 at 68:13-69:4, 70:23-71:9 (Wasserstein Dep.)).

Upsher-Smith appreciated its obligations to Schering. (Troup 5509:13-5510:7). It fulfilled its obligations to manufacture Prevalite for Warrick upon Schering's request and did so on an expedited basis. (SPX 452 at 0020-21; SPX 455; USX 465 at 02270-71). It also provided Schering with information relevant to the licensed products, although in the case of Niacor-SR clinical data, Upsher-Smith was not always able to satisfy Schering's pressing requests for information as promptly as Schering would have liked. (UPF 596-605, 634-659, 677-704). Nonetheless, Upsher-Smith persisted in completing its clinical studies on Niacor-SR for Schering's benefit — at a cost of approximately $1.5 million — after Upsher-Smith had put on hold its own efforts to submit an NDA in the United States for the product. (Halvorsen 3902:13-20, 3952:24-3957:16, 3963:23-3964:25, 3987:21-3988:14, 3989:9-25; Kralovec 5010:24-5011:7;

USX 342; USX 555; USX 556; USX 1226; CX 1097 at 153369 (ANDA strategy memo noting Schering)).[5]

Contrary to Complaint Counsel's implication, there was nothing unusual about the fact that Schering's upfront royalty payments were not contingent on U.S. regulatory approval. *See* CAB:31-32. The products were already developed; three of the six were already on the U.S. market. (UPF 46, 449-55, 699). Given that Schering was receiving licenses solely for ex-U.S. territories (except in the case of Prevalite, which already had U.S. approval), there was no need to link payment to U.S. regulatory approval. As Levy conceded repeatedly, U.S. regulatory approval was not a prerequisite for foreign regulatory approval. (Levy 1936:2-1937:20, 2082:24-2083:3).

E. Judge Chappell's Credibility Determinations Are Supported By Documentary Evidence And Should Be Accorded Deference

The Supreme Court has held that an administrative agency must give substantial weight to an ALJ's assessment of "witnesses he hears and sees." *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 495 (1951). Consistent with *Universal Camera*, the Commission has long applied a deferential abuse-of-discretion standard to ALJ determinations of fact based on credibility determinations:

> The Commission, absent a clear abuse of discretion or unusual circumstances, will not interfere with the examiner's ruling on the issue of credibility. The examiner's proximity to the proceedings, his presiding thereover, and his ability to observe the witnesses' demeanor clearly place him in the most favored position with respect to any rulings on the credibility of a witness.

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[5] While Niacor-SR was certainly the "crown jewel" among the products licensed to Schering, Complaint Counsel wrongly suggest that the other five products had insignificant value. (CAB:22 n.14). Consideration of these other products was a material part of the transaction presented to the Schering Board. (Troup 5431:6-5433:11; Kerr 6300:21-6502:1; *see also* Kerr 6312:3-16 (Valuation analysis over five-year period shows a value of $10.1 million and over a ten-year period the value would have been $17 million)).

In the Matter of Lenox, Inc., 73 F.T.C. 578, 604 (1968); *accord In the Matter of Horizon Corp*., 97 F.T.C. 464, 857 n.77 (1981) ("Absent a clear abuse of discretion, the Commission will not disturb on appeal the ALJ's conclusions as to credibility."). This deference applies to an ALJ's assessment of both fact and expert witnesses. *In the Matter of Brake Guard Prods. Inc.*, 125 F.T.C. 138, 234 n.17 (1998).

Complaint Counsel premised their case on the theory that numerous businesspeople concocted a bogus licensing transaction as a "veil," "cover" or "disguise" for a payment to delay generic competition. (CCTB 2-3, 6, 8, 26; ID 106). This theory necessarily suggests that the business people involved knew they were doing something improper, and they sought to hide it. In such a case credibility is critical.

In finding that the Agreement was a *bona fide* arms-length transaction and that Schering's royalty payments constituted fair value, Judge Chappell necessarily relied on his assessment of witness credibility. Indeed, in addition to the credibility assessments implicit throughout the Initial Decision, Judge Chappell made numerous express findings on the credibility of witnesses. For example:

- "The ***fact testimony at trial was unrebutted and credible*** in establishing that the licensing agreement was a *bona fide* arms-length transaction, and that Schering's royalty payments to Upsher-Smith were payments for the products being licensed to Schering, together with certain production rights." (ID 107 (emphasis supplied)).

- "The opinion testimony of Complaint Counsel's expert witnesses, based largely upon theory, did not impeach that unrebutted and credible fact evidence." (ID 107).

- "***Doctor Levy's testimony is contradicted by the greater weight of evidence***. . . . Furthermore, ***Dr. Levy's testimony is accorded less weight*** for three reasons. . . . Third, ***Dr. Levy's conclusion*** [regarding the parties post-deal conduct] ***is rebutted*** by the evidence Respondents presented on their post deal conduct ***and discredited*** because Levy did not review many of the documents reflecting the parties' communications and continued work on the licensed products. F. 315-18." (ID 109 (emphasis supplied)).

Indeed, Complaint Counsel's theory of the case — that executives at Schering and Upsher-Smith knowingly engaged in an anticompetitive agreement and sought to conceal it — calls for a determination of whether the sworn denials of these executives are credible.

Complaint Counsel unfairly suggest that Judge Chappell thought the case should "stand or fall on whether respondents made testimonial confessions." (CAB:24). Judge Chappell never suggested that; among his numerous findings, he simply stated that "[n]o fact witness had testified that the payments provided for in the June 1997 Agreement were not for Niacor-SR and the other products Schering licensed from Upsher-Smith." (IDF 162). Judge Chappell plainly did not accept these sworn denials uncritically. As his highly-detailed Initial Decision demonstrates, Judge Chappell meticulously analyzed ***all*** the evidence.

Complaint Counsel, citing *United States v. United States Gypsum Co.*, 333 U.S. 364 (1948) and similar cases, also chastise Judge Chappell for supposedly crediting testimony contradicted by contemporaneous documents. (CAB:1-2, 23-24, 30). Again, the Initial Decision reflects that Judge Chappell thoroughly scrutinized all of the evidence, focusing specifically upon whether the testimony of Schering and Upsher-Smith representatives was consistent with contemporaneous documents. Indeed, Judge Chappell expressly found that "[c]ontemporanous documentary evidence" "such as Mr. Audibert's commercial assessment and Schering's Board Presentation" corroborated the trial testimony that the license agreement was a *bona fide* arms-length transaction and that the royalty payments were for the licenses and supply rights. (ID 107).

Judge Chappell was right: Documentary evidence uniformly corroborated the fact testimony of the Schering and Upsher-Smith witnesses. For example, internal Upsher-Smith documents corroborated their investment in Niacor-SR (USX 395; CX 1097; USX 329); their

high expectations for Niacor-SR (USX 1563); and their desire to find a European marketing partner (USX 132; USX 544; USX 133; USX 538; USX 596-98; CX 880). Internal Schering documents corroborated Schering's interest in a sustained-release niacin product. (SPX 21; CX 543; CX 550; SPX 619). Analyst reports and stock tables corroborated the value placed on Kos's Niaspan in the marketplace in mid-1997. (USX 535; SPX 225; USX 825). Numerous documents contemporaneous with the negotiations — Upsher-Smith's 52-page dossier (CX 1042), the commercial assessment of Schering's James Audibert (SPX 2), the Schering Board Presentation (CX 338) — corroborated the *bona fides* of the negotiations. Reams of voluminous documents (USX 1178 through 1266) corroborate Upsher-Smith's post-deal activity regarding development of the licensed products. Contemporaneous documents demonstrated Upsher-Smith's continuing communications with Schering regarding the development (*see, e.g.,* SPX 452; USX 732; USX 786; USX 189; USX 366; USX 256; USX 674; USX 219; USX 665; SPX 251), and established Upsher-Smith's manufacturing and delivery of licensed product to Schering (USX 672; USX 452; USX 674). Numerous documents also corroborate the disappointing sales results of Kos's Niaspan, the corresponding crash of its stock price, and the reconsideration of Niacor-SR by Upsher-Smith and Schering. (USX 1027-29; CX 1088; CX 1090; USX 1226; USX 1258; CX 1111).

Thus, Judge Chappell did not blindly credit "self-serving" testimony. He analyzed the extensive documentary evidence and found that the witnesses' testimony was corroborated by contemporaneous documents. As the Commission has recognized, when "self-serving testimony" is so corroborated, it should be credited. *See In the Matter of The Grand Union Co.*, 102 F.T.C. 812, 1068, 1079 (1983) (relying on "self-serving" testimony of respondents' official that was "consistent with other record evidence"); *see also In the Matter of Gen. Motors Corp.*,

99 F.T.C. 464, 570 n. 29, 572 & n.36 (1982) (relying on respondent's testimony "despite its obvious self-serving nature").

In short, on the critical question of whether the Agreement involved a payment for something other than the bundle of licensed products and supply rights, Schering and Upsher-Smith's witnesses provided testimony amply corroborated by business records. Judge Chappell, who was uniquely situated to assess the testimony and the demeanor of the witnesses, found the testimony to be credible and, indeed, unrebutted. Under Supreme Court and Commission precedent, Judge Chappell's finding here should not be disturbed.

II. NO ANTICOMPETITIVE EFFECTS WERE PROVED BUT SUBSTANTIAL PROCOMPETITIVE EFFECTS WERE PROVED

Complaint Counsel did not bear its burden of proving any anticompetitive effect. The evidence at trial established that the Schering/Upsher-Smith Agreement had powerful procompetitive benefits. In their appeal brief, Complaint Counsel devote merely a single sentence in response to these procompetitive benefits, describing them as "unexplained." (CAB:69). In fact, the procompetitive benefits are amply explained. They are also unrebutted, and their existence forecloses any *per se* condemnation of the Agreement.

A. Complaint Counsel Failed To Prove Delay

Complaint Counsel never proved that an entry date earlier than September 1, 2001 was possible. (Bresnahan 901 (conceding no evidence that the parties considered an entry date earlier than September 1, 2001)). Schering never offered an earlier date. (IDF 137; Troup 5500). Complaint Counsel's delay case (CAB:56-63) amounts to mere rhetorical arm waving. Complaint Counsel candidly admit the absence of proof, asserting that their case requires "no proof" (CAB:60) of anticompetitive effect, and appealing to "common sense" and "basic economics" without any record citation. The assertion that "reduction in uncertain competition

itself is an anticompetitive effect" (CAB:62) ignores the fact that while the patent litigation is pending, there is ***no competition*** from the defendant generic firm. *See* II.B. *supra*. Consumers gain nothing from generics that are sidelined awaiting termination of drawn-out lawsuits.[6]

If Upsher-Smith had continued to litigate, there was no guarantee of success or of the timing of that success. And Adelman testified that the litigation in the trial court alone could last five years and with the appeals could have dragged on for eight years. (Adelman 7773-74).

Moreover, Upsher-Smith greatly expanded its production capacity in order to launch M20. The ramp-up to launch took 27 months and was the equivalent of the "Normandy landing." (UPF 808; Troup 5486; Gould 5116).

Thus, not only did Complaint Counsel fail to prove any payment for delay, Complaint Counsel failed to prove delay.

B. Upsher-Smith Demonstrated That The Agreement Had Substantial Procompetitive Benefits

1. The Agreement Halved The Remaining Life Of Schering's Patent

Schering originally offered to license Upsher-Smith to launch M20 in 2005 or 2006. (IDF 133, 134; Troup 5412). Troup's negotiating persistence moved Schering to accelerate the entry date. (IDF 134, 137; Troup 5425-26). The Agreement ultimately took five years off the patent's remaining nine years, (IDF 157), "permitt[ing] entry 60 months before the expiration of

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[6] Complaint Counsel's reliance on *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001) — (CAB:60-61) — is misplaced. The United States proved a wide variety of non-speculative, anticompetitive effects through record evidence, *id*. at 61 (OEM computer manufacturers unable to install a second browser in addition to Internet Explorer); *id*. at 61-62 (OEM prohibited from modifying initial boot sequence thwarting internet access providers). Oddly, Complaint Counsel jump to the opinion's causation section, *id*. at 79 — an issue only reached after tangible anticompetitive effects were proven. Moreover, the settlement here did not "squash" the future competitors. *Id*. Instead, its patent-shortening guaranteed early marketing of M10 and M20.

the patent" (Bresnahan 899), and removing ***more than half*** of the remaining patent life (measured from June 1997 to September 2006). (IDF 386; Bresnahan 894-95 (110 months off remaining patent life; 60/110 months is 54% off) *see* USX 1011). *See* Bresnahan 894 (acknowledging Agreement is five months better for consumers than the midpoint of the remaining patent life February 2002).[7]

Dr. William Kerr, the only expert to methodically estimate the timing of average litigation outcomes for the patent lawsuit using conservative assumptions, (Kerr 6262-77), estimated that the average likely date for consumers to receive M20 was February 2003, (UPF 488, 489; Kerr 6273-74). The "settlement accelerated the potential entry date by 17 months." (Kerr 6274; UPF 490). Absent the settlement, it is virtually certain that Klor-Con M20 would not be on the market and available to consumers today.

2. The Agreement Generated New Production Investment And Greatly Increased Upsher-Smith's Potassium Output

Upsher-Smith was not about to invest in the commercial production of M20 unless it was certain it could market M20. (UPF 715-16; Troup 5483). The uncertain outcome of the litigation prevented Upsher-Smith from spending monies on the expansion of the Minnesota plant or IPC. (Kralovec 5038; Gould 5136, 5176). Absent settlement, the Schering patent could have blocked Upsher-Smith until September 5, 2006. (ID at 100).

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[7] Schering knew that Upsher-Smith was legally barred from marketing M20 before the May 1998 expiration of the thirty-month stay. From that date, the Settlement removed 60% of the patent's remaining life. (UR-CPF 165). From FDA M20 approval in November 1998 (IDF 391; ID 106) to 2006, the Agreement removed more than 64% of the patent's life. (UR-CPF 165).

Launching M20 during the pendency of the lawsuit was not an option; it would have constituted "financial suicide" given the catastrophic damages — potentially trebled — Upsher-Smith faced by launching but ultimately losing the litigation. (Kralovec 5038; IDF 391). Had that occurred, Upsher-Smith would have "disappeared" as a potential entrant. (Bresnahan 666-67). Kerr described as "intolerable" the risk of launching before resolution of a patent case. (Kerr 6259-62 (describing draconian consequences); Kerr 6902-03 ("Upsher-Smith and other generic manufacturers in similar situations would be foolhardy to enter the market with the lawsuit pending."); Kerr: 6260-61 (risk "intolerable in most instances"); Kralovec 5038; IDF 391; ID 106).

Upsher-Smith's refusal to launch before final resolution of the patent litigation is typical of generic firms defending patent cases. (Herman 2484-568; IDF 391); *see also* IDF 390-91; *In re Tamoxifen Citrate Antitrust Litig.*, --- F. Supp.---, 2002 WL 1962125, at *5 (E.D.N.Y. Aug. 26, 2002). Complaint Counsel's industry witness confirmed that generic manufacturers will not launch their product before resolution of patent litigation. (Rosenthal 1580-83, 1578-81 (FDA-approved generics for Prilosec and Cardizem not marketed due to pending patent litigation)).

However, once the litigation exposure was eliminated, Upsher-Smith could invest monies in the expansion of its Minnesota facility and IPC's Kentucky plant. Upsher-Smith invested more than $10 million to expand production capacity for M20 at Upsher-Smith and IPC. (Troup 5483-86; Kralovec 5042). Upsher-Smith invested more that $7 million in a 17,000-square-foot expansion of their factory and installed new mixing, tableting, bottling, and packaging equipment for its potassium supplement, expanding potassium output. (UPF 722-34). Upsher-Smith financed the $2.75 million upgrade of IPC's granulation facilities so that IPC could meet Upsher-Smith's demand for spray-coated potassium, M20's primary ingredient. (UPF 739-61,

767-69). The investment and upgrade of the two facilities enabled IPC, which had no capacity dedicated to Upsher-Smith, to support a full commercial (100 million tablet) launch. (UPF 740; Gould 5124). Upsher-Smith not only doubled its total potassium production, but it did so without compromising the manufacturing of other products, previously a critical problem for Upsher-Smith. (UPF 717, 722-23; Gould 5129-30; Kralovec 5047).

The Agreement gave Schering low-cost additional production capacity for M20 and five other products via six supply agreements. CX 348 at ¶¶7-10. Schering won the right to call on Upsher-Smith for "all" of its needs for Klor-Con 8, 10 and M20 at Upsher-Smith's internal cost — i.e., with no additional margin. *Id*.¶8. Schering also won valuable low-cost supply arrangements from Upsher-Smith for Niacor-SR, Prevalite and Pentoxifylline for all of its needs, typically at Upsher-Smith's costs. *Id.* at ¶¶7, 9-10. These supply-expanding arrangements had value to Schering (Bresnahan 951-57) and required Upsher-Smith to maintain the expanded production capacity to meet this additional demand.

Agreements that lead to increased output are procompetitive. *See, e.g., Broadcast Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 23 (1979) (joint selling arrangement among music composers that increased total output of musical compositions sold); *Association of Indep. Television Stations, Inc. v. College Football Ass'n,* 637 F. Supp. 1289, 1296 (W.D. Okla. 1986) ("[c]ooperative activities among competitors may increase the aggregate output of the sellers and thus serve the goals of competition"). Agreements that stimulate investment in production capacity are procompetitive. *See Continental T.V., Inc. v. GTE Sylvania, Inc.,* 433 U.S. 36, 55 (1977) (holding restraint procompetitive where it induces retailers to make the "investment of capital and labor that is often required in the distribution of products"); *New York v. Anheuser-Busch, Inc.,* 811 F. Supp. 848, 876 (E.D.N.Y. 1993) (holding restrictions procompetitive where

agreement "helped solidify the wholesalers' financial base, enabling them to undertake the expensive investments and activities" producing pro-competitive effects).

No Complaint Counsel witness addressed the patent litigation's disincentive to production investment. Bresnahan did not study the impact of litigation uncertainty on Upsher-Smith's ability to invest in expanded output. (Bresnahan 906-07).

3. The Settlement Permitted The Entry Of A Second Potassium Product: M10

Schering's lawsuit challenged only the M20 product. (IDF 159). But without a global settlement, Upsher-Smith could have been subject to a separate lawsuit blocking it from marketing M10. (Kerr 6253). Instead, Upsher-Smith "managed to . . . put the M10 into this agreement so as to obviate the possibility of another lawsuit concerning the 10 . . . since the original lawsuit was only the 20." (Troup 5471). As Dr. Kerr testified: "[T]his settlement agreement essentially allowed both of those products to come in. It not only ended the litigation that was in existence for the M20, it eliminated the prospect that in order to get the M10 to market, Upsher would have had to fight another lawsuit." (Kerr 6335).

Introduction of a second, new potassium product is a procompetitive achievement. *See, e.g., United States v. Brown Univ.,* 5 F.3d 658, 674-75 (3d Cir. 1993) (reversing for full Rule of Reason analysis; "[e]nhancement of consumer choice is a traditional objective of the antitrust laws and has also been acknowledged as a procompetitive benefit") (citation omitted); *NCAA. v. Bd. of Regents of the Univ. of Okla.,* 468 U.S. 85, 102 (1984) (recognizing the procompetitive benefits of NCAA in "widen[ing] consumer choice — not only the choices available to sports fans but also those available to athletes"); *Wisconsin Music Network, Inc. v. Muzak Ltd. P'ship,* 5 F.3d 218, 222 (7th Cir. 1993) (subscription music service offered procompetitive benefits where it "enhances competition by increasing the available choices for music service customers").

Bresnahan did not disclaim that the Agreement eliminated the risk of a lawsuit over M10.

4. The Agreement Saved Private Resources, Permitting Additional R&D And Potassium Marketing

"Society benefits when settlements allow the parties to conserve resources and avoid transaction costs, which may include not only legal fees, but also the time and distraction of the parties and their personnel." (ID 100 (Professor Mnookin)). In this case, Schering filed the '743 lawsuit "for the legitimate purpose of defending its patent," (IDF 128), and the litigation was hard-fought, (IDF 131 (suit: "vigorously contested"; "taking longer than Upsher-Smith had anticipated"; "particularly rancorous"); Cannella 3815 ("vigorously contested"); Kralovec 5033; Troup 5405-06; Compl. ¶40 ("strongly contested")). CFO Kralovec recalled that the lawsuit was "very hostile" (Kralovec 5433).

The litigation was the most expensive lawsuit in Upsher-Smith's history, (Dritsas 4892-93), costing Upsher-Smith nearly $3 million in fees from December 1995 through June 1997 (Kralovec 5035; Cannella 3818-24) — double Upsher-Smith's M20 development costs, (Dritsas 4895).

Potassium was Upsher-Smith's top-selling drug, (USX 1549 at USL 13873), but the lawsuit caused belt-tightening, with cuts in potassium marketing and promotion budgets. (Dritsas 4664 ("I know from a marketing perspective, [the lawsuit] affected my budget, it affected what I had, the resources I had available just to promote the products I had.")).

Resources spent on the patent lawsuit traded off with resources for productive and procompetitive uses. (Addanki 5817-18 ("litigation consumes huge amounts of resources . . . having to retain lawyers and experts and so on, so there is a tremendous opportunity cost in private resources, because . . . business people, who really should be running their businesses but are distracted with litigation instead."); UPF 706; Dritsas 4749-50, 4894-95 (marketing plans to

vigorously target K-Dur 20 immediately after settlement)). The "cloud of litigation" caused a "drain on resources," compromising the ability of Upsher-Smith's five managers to "concentrate on other things like new products, sales and marketing." (Troup 5406).

On cross-examination, Bresnahan acknowledged the opportunity costs of the Schering lawsuit for Upsher-Smith: monies spent on litigation were unavailable for marketing or R&D. (Bresnahan 908-10).

5. The Agreement Earned Upsher-Smith A Return On Its R&D Investment, Encouraging Innovation

Through the Agreement, Upsher-Smith earned a return on its substantial R&D expenditures in Niacor-SR and the other drugs licensed. Upsher-Smith's Niacor-SR research program was the biggest R&D project in the company's history (Halvorsen 3902), and Upsher-Smith spent $15 million on the R&D for Niacor SR — 80% of Upsher's entire R&D budget. (IDF 286). Upsher-Smith spent an additional $1.3 million in R&D on M20. (Dritsas 4895).

Patents provide an incentive to encourage R&D and innovation. (Bresnahan 8140-41 ("without patents or government incentives there would be too little innovation.")). Licensing of intellectual property is procompetitive. U.S. DEP'T OF JUSTICE AND FEDERAL TRADE COMMISSION, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY, Sec. 2.0.c. (April 6, 1995) ("intellectual property licensing allows firms to combine complementary factors of production and is generally procompetitive."). "[T]he direct pro-competitive benefit of the patent settlement . . . is its resulting in a sharing of intellectual property, so it's disseminating and increasing the base of use of intellectual property. So that's directly pro-competitive." (Addanki 5818).

6. The Agreement Permitted Upsher-Smith To Unleash Other Generics, Further Growing Output During The 180-Day Period

During the 180-day period, consumers received ***three*** new generic potassium chloride drugs as a result of Upsher-Smith's license — a point conceded by Bresnahan. (Bresnahan 929 (M20, Qualitest and Schering's Warrick generic)). A unique feature of the settlement was that Upsher-Smith could aggressively resell its M20 product to Qualitest so that Qualitest could leverage its low-priced reputation for generic drugs. (Dritsas 4677). Qualitest sold M20 during the 180-day period. And Qualitest alone determined the resale price of this M20 product (Dritsas 4680-81), bringing added price competition to consumers.

7. The Agreement Expanded Distribution For Six Pharmaceutical Products And Disseminated Intellectual Property

The Agreement gave Upsher-Smith a complementary marketing outlet for six of its pharmaceutical products: Klor Con 8, 10, M20, Prevalite, Pentoxifylline, and Niacor SR. In 1997, Upsher-Smith had no sales force or marketing presence outside the United States. (IDF 197). The Settlement Agreement gave Upsher-Smith access to geographic markets where it lacked of a sales force. (Kerr 6357).

8. The Agreement Saved Scarce Public Resources

The pendency of the lawsuit imposes direct societal costs. Patent settlements are pro-competitive. "Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming . . . By such agreements are the burdens of trial spared to the parties, to other litigants waiting their turn before over-burdened courts, and to the citizens whose taxes supports the latter." *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976); (ID 99).

C. The June 1997 Agreement Must Be Analyzed Under The Rule Of Reason

The presence of procompetitive benefits in this case means that the Agreement cannot be condemned as *per se* illegal. *Per se* treatment is appropriate only when — in contrast to this case — the challenged conduct lacks "any redeeming virtue," *Northern Pac. Ry. v. United States*, 356 U.S. 1, 5 (1958), or "plausible procompetitive benefit," *California Dental Ass'n v. FTC*, 526 U.S. 756, 778 (1999); *see also United States v. Cooperative Theatres of Ohio, Inc.*, 845 F.2d 1367, 1372 (6th Cir. 1988) (*per se* standard applied only after "defendants failed to articulate a single procompetitive justification for the horizontal restrictions.").

Per se condemnation is also inappropriate because Complaint Counsel have advanced the novel theory that a side license masked a "payment for delay." Courts will apply the *per se* rule only when judicial experience has shown, ***time after time***, that similar agreements adopted in similar circumstances have substantial and "pernicious" anticompetitive effects. *Northern Pac. Ry.*, 356 U.S. at 5; *see also Northwest Wholesale Stationers, Inc. v. Pac. Stationery & Printing Co.*, 472 U.S. 284, 289-90 (1985) (*per se* treatment appropriate only where conduct "always or almost always tend[s] to restrict competition and decrease output.") (citation omitted); *Smith v. Pro Football, Inc.*, 593 F.2d 1173, 1181 (D.C. Cir. 1978) (*per se* treatment appropriate only when "the strength of unambiguous experience " shows that the practice is a "naked restraint[] of trade with no purpose except stifling of competition.") (citation and footnotes omitted).[8]

No reported antitrust case has ever embraced a theory akin to that advanced by Complaint Counsel. Bresnahan testified that there was no published economic literature on "reverse payments" before April 2001. (Bresnahan 644-45). The entire empirical basis for Bresnahan's

[8] Moreover, the Bresnahan Test for reverse payments requires proof of monopoly power — a requirement at odds with the *per se* test.

test consists of the two agreements at issue in this case. (Bresnahan 1021-22). Bresnahan has not published anything on "reverse payments" and has no plans to do so. (Bresnahan 644-45, 658).

The "considerable judicial experience" that Complaint Counsel proffer amount to two district court cases — *Cardizem* and *Terazosin* (CAB:42) — both decided long after the Agreement and both certified for interlocutory appeal. Significantly, the standard for interlocutory appeal requires that the case "involve[] a controlling question of law as to which there is substantial ground for difference of opinion." 28 U.S.C. § 1292(b). Unlike the Agreement, however, neither *Cardizem* nor *Terazosin* involved an intellectual-property side license as part of a global settlement. Neither case involved a patent-shortening settlement. Both cases expressly extended Hatch-Waxman's 180-day exclusivity periods; here the Agreement does not address the exclusivity period at all.

Per se treatment is also unsuitable here because this case involves the settlement of an intellectual property dispute. Since *Standard Oil Co. v. United States*, 283 U.S. 163 (1931), the Supreme Court has accorded special antitrust treatment to intellectual property agreements, and courts have routinely applied the Rule of Reason to markets affected by exclusionary statutes such as the Patent or Hatch-Waxman Acts. *See Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999) ("some measure must guarantee that the jury account for the procompetitive effects and statutory rights extended by the intellectual property laws"); *In re Indep. Serv. Orgs. Antitrust Litig*., 203 F.3d 1322, 1326 (Fed. Cir. 2000) (Court must give "due consideration to the exclusivity that inheres in the patent grant"), *cert. denied sub nom. CSU, LLC v. Xerox Corp*., 531 U.S. 1143 (2001).

D. The Net Competitive Effects Were Not Weighed

Bresnahan's critique of the Settlement was based entirely on his three-pronged Bresnahan Test — *see* Intro. *supra* (ID 85; Bresnahan 655-56) — a test not even reproduced in Complaint Counsel's brief. No "fourth" prong of the Bresnahan Test evaluates or weighs pro-competitive aspects of settlements. (Bresnahan 658). Bresnahan simply failed to weigh the foregoing benefits of the Agreement.

In short, Complaint Counsel presented no Rule of Reason case because they did not prove anticompetitive effect — a fatal flaw in Complaint Counsel's proof. *California Dental*, 224 F.3d at 958 (FTC "failed to demonstrate substantial evidence of a net anticompetitive effect" when procompetitive benefits outweighed economic harms).[9]

III. SCHERING WAS NOT A "MONOPOLIST" IN K-DUR 20 IN JUNE 1997

The only witness who testified that the June 1997 Agreement was "anti-competitive" was Bresnahan, based on his Test. (Bresnahan 418-19, 655-56). Bresnahan's Test requires proof that Schering was a "monopolist" in June 1997. (IDF 414-15; Bresnahan 660). If Schering was not a "monopolist," then the Agreement is not "anticompetitive." (IDF 416; Bresnahan 661). Although Complaint Counsel seem eager to jettison the Bresnahan Test ? neglecting to mention

[9] Complaint Counsel did not attempt to meet their burden of demonstrating a reasonable less restrictive alternative; they had no witness. *United States v. Brown Univ.*, 5 F.3d 658, 679 (3d Cir. 1993). Theoretical less-restrictive alternatives are irrelevant; Complaint Counsel must prove that the other alternatives are reasonable and practical, *M&H Tire Co. v. Hoosier Racing Tire Corp.*, 733 F.2d 973, 987 (1st Cir. 1984), without causing significant additional costs, *County of Tuolumne v. Sonora Comm. Hosp.*, 236 F.3d 1148, 1159 (9th Cir. 2001). The settlement was an integrated whole, and attempting a second separate transaction would have created substantial transaction costs. Moreover, Complaint Counsel never proved that a separate licensing transaction would have meant earlier entry; September 1, 2001 was the earliest date Schering offered.

it in closing argument, post-trial briefing or this appeal ? shunning Bresnahan leaves them with no evidence of an "anti-competitive" agreement.

The record demonstrates that Schering was not a "monopolist." Complaint Counsel failed to prove that K-Dur 20 was priced at a supracompetitive level or that Schering restricted K-Dur 20 output:

- In June 1997, K-Dur 20 had only 33% market share of potassium products, according to IMS. (IDF 402; CX 62 at 089327).[10]
- Contemporaneous documents proved K-Dur 20 was one of more than 20 potassium products. (IDF 33 ("at least 23 potassium products"); IDF 35; USX 277 ("at least 24" potassium products); IDF 406 (1997: "over 30 products competing"); CX 18 at 2300040 (K-Dur 20 in "crowded" market.)).
- Complaint Counsel's customer witnesses, from United Healthcare (Dean Goldberg) and Merck-Medco (Russell Teagarden) — both pharmacists — attested to "therapeutic equivalence" of potassium products to K-Dur 20. (IDF 49-55, 89).
- Schering's substantial investment in K-Dur 20's promotion and rebates drove sales. (IDF 80, 114-16, 409, 411-13; ID 117-18). Prior to September 2001, Schering spent more than $136 million in rebates — Schering was "competing on price through rebates" with other products (IDF 115-16).
- Schering's ***output*** of K-Dur 20 ***grew*** steadily due to promotion. (IDF 410). K-Dur 20's output rose 25% between 1997 and 2001. (IDF 410).
- Complaint Counsel adduced no evidence of supracompetitive pricing. Bresnahan made no comparison of K-Dur 20's price to the price of other potassium supplements. (IDF 90, 92). Bresnahan performed no econometrics or even simple price-differential statistics. (IDF 90-93). Bresnahan had no pricing data for any potassium product. (Bresnahan 867-68).

[10] Schering's documents tracked market share in "TRX" — total prescriptions — as measured by IMS. CX 13 at SP003044. Prescriptions are the appropriate measure of market share as demand for potassium begins at the prescription pad. (Bresnahan 696; 8133).

- K-Dur 20 was not the most expensive potassium tablet. (Addanki 5741 ("at no point was K-Dur 20 the highest price potassium chloride supplement"); Addanki 5741-46; SPX 2068, SPX 2069).

- There were no barriers to entry. (IDF 405-08). Numerous manufacturers entered. (IDF 405-07). Bresnahan did no analysis of entry. (IDF 405). No evidence established that other firms could not expand output. (IDF (407-08)).

A. Complaint Counsel Failed To Prove A K-Dur-Only Product Market

Complaint Counsel presented only Bresnahan for relevant product market, asserting a 20 mEq-only product market. (IDF 30). Bresnahan's *ipse dixit* is not proof. *See Murrow Furniture Galleries, Inc. v. Thomasville Furniture Indus., Inc.*, 889 F.2d 524, 528 (4th Cir. 1989) (economist's assertion of narrow market rejected); *Bailey v. Allgas,* 148 F. Supp.2d 1222, 1246 (N.D. Ala. 2000) (expert opinion on market power and relevant market "lacks sufficient evidentiary foundation") *aff'd,* 284 F.3d 1237 (11th Cir. 2002). Bresnahan performed no comparison of K-Dur 20's price to other potassium products, because he lacked pricing data. (IDF 90, 92, 419-20, 422)

1. Other Potassium Products Are Therapeutically Equivalent To K-Dur 20

Complaint Counsel concede that K-Dur 20 is "one of many potassium supplements sold in the United States." (CAB:4). More than 23 firms sold potassium in 1997. (IDF 33; CX 43 at 020664-69; UPF 52; UPF 57 (USX 630 — over 50 potassium products in October 1997)). Multiple witnesses provided substantial, unrebutted testimony as to the "therapeutic equivalence" of these products to K-Dur 20. (ID 38-48; UPF 89-95).

Complaint Counsel's customer witnesses testified that all potassium products treat potassium deficiencies and are interchangeable with K-Dur 20. (IDF 49-55; UPF 112, 119). Customers confirmed that doctors prescribe two 10 mEq potassium tablets to substitute for K-

Dur 20. (UPF 111-12; UPF 117-19; IDF 49-55). Judge Chappell himself asked Goldberg whether two Upsher-Smith 10-meq Klor-Con wax-matrix tablets would have the same therapeutic effect as K-Dur 20; Goldberg testified unequivocally that taking two 10-mEq tablets would "deliver the same amount of potassium over that eight to ten-hour time period" as one K-Dur 20. (Goldberg 174-75; IDF 45).

2. *Brown Shoe* Indicia Do Not Establish A K-Dur-Only Market

Judge Chappell followed the leading U.S. Supreme Court case on product market. *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) ("The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it"); ID 87-88 (collecting cases), *see also* UPTB at 63-64 (collecting cases). *Brown Shoe* established "practical indicia" to establish a "submarket" that include "industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." 370 U.S. at 325. The record evidence weighs convincingly against a K-Dur-20-only submarket.

a. Industry Or Public Recognition

No industry witness supported a distinct K-Dur 20 submarket. Courts examine industry publications, customers and marketing documents. (ID 92). Complaint Counsel's customer witnesses viewed K-Dur 20 as only one of many potassium supplements. (IDF 50-55; ID 92).

- **IMS Trade Data.** IMS has a single potassium chloride category, 60110, in which K-Dur 20 is one of more than 30 products sold by more than 25 firms. (Bresnahan 889; IDF 83; UPF 98-103; USX 822). Over 30 supplements are within the market. (Addanki 5685-87); (Dritsas 4712 (approximately 50 firms)).
- **No Trade Periodicals.** Bresnahan could identify no pharmaceutical trade periodicals that treat K-Dur 20 as a unique product or category. (IDF 81).

- **Authoritative Medical Treatises.** Bresnahan reviewed no medical treatises used by physicians choosing potassium treatments. (Bresnahan 8154; UPF 104-10).

- **No Customer Recognition**. Merck-Medco has no separate listing for 20-mEq potassium in its formulary. (IDF 51; UPF 113). In 1993-96, Merck-Medco did not list K-Dur 20 on its formulary. (IDF 51). Managed care used alternatives to K-Dur 20. (IDF 49-55; UPF 112, 119; CX13 at 003044; Addanki 5705-07).

- **No Pharmacist Recognition.** All three pharmacists — Goldberg, Teagarden, and Upsher-Smith's Lori Freese — agreed that two 10-mEq potassium tablets were "therapeutically interchangeable" with K-Dur 20. (UPF 121).

Apothecon's Marketing Documents. {

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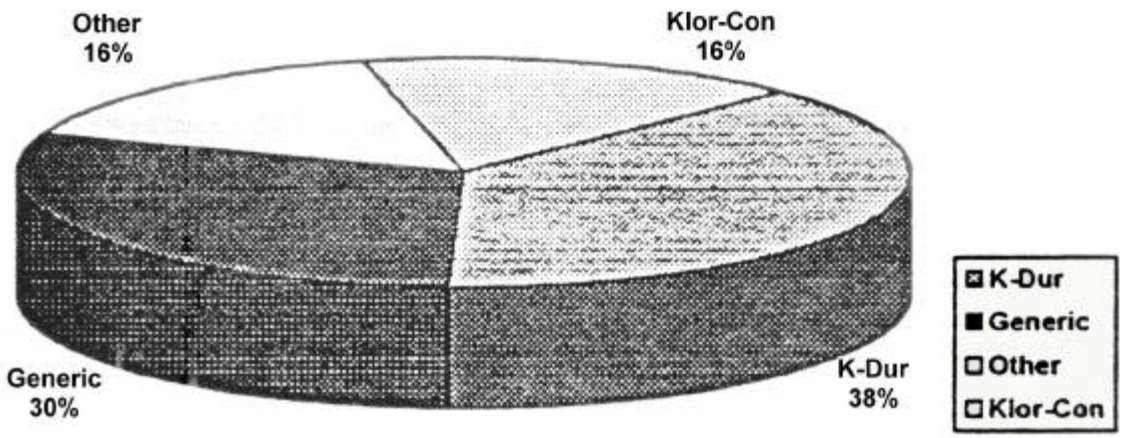
(Bresnahan 1066-71; USX 822 (*in camera*)).

Schering's Marketing Documents. Schering viewed the potassium market as "crowded." (IDF 61; UPF 135, CX 746 at SP2300370). Schering's marketing plans listed many competing potassium products. (IDF 60; 62-63; CX 746 at SP2300380-83 (15 other products); CX18 at SP2300039 (1997 K-Dur Marketing Plan "[g]eneric competition continues to grow at the expense of K-Dur 20"); CX 13 (low cost alternatives limiting K-Dur); CX20 at SP004040; Bresnahan 709-10, 720-21, 814, 816-17, 824-25; Addanki 5708).

Schering always tracked the growth of K-Dur 10 and 20 (together as "K-Dur") in terms of total prescriptions against the overall potassium market, using IMS data:



SP 004034
Confidential

(CX 20 (1998 K-Dur Marketing Plan, August 1, 1997) at SP004034; IDF 60).

Upsher's Marketing Documents. Upsher-Smith saw K-Dur 20 as a "major competitor" to Upsher-Smith's Klor-Con products. (IDF 64-69). Upsher-Smith wrote that K-Dur 20 "competes directly against the [Klor-Con] 8 and 10 mEq strengths." (CX740; IDF 69; USX 1549 at USL13858 and 13861-63 (1996 Marketing Plan: K-Dur 20 is "major competitor[] to focus on" and that K-Dur 20 "offer[s] competitive pricing."); USX 626 at USL15234-35 (K-Dur 20 a threat to 10-mEq sales); USX 480 (promotions comparing Klor-Con 10 with K-Dur 20); IDF 67; Dritsas 4691-92 (K-Dur 20 "major competitor[] [for Upsher-Smith] to focus on"); IDF 70-75 (Upsher-Smith promotions urging two Klor-Con 10s for one K-Dur 20); Addanki 5712-13).

Upsher-Smith's documents describe a vibrant, fragmented market. (USX 630 at USL15328-29 (l9 different competing products); USX 626 at USL15228 ("In the 10/20 mEq market, the focus has been on price with continued growth from generics such as Ethex . . . The

major brands have started to trade price for volume to compete with strong generic competition."); USX 410 at 190292). Upsher-Smith viewed the market having "multiple competitors, all with different types of promotional and pricing strategies . . . . [t]here were just a number of different players, and it was a fairly crowded market." (Dritsas 4663).

b. Product's Peculiar Characteristics And Uses

K-Dur 20 does not have "peculiar characteristics and uses." (IDF 84). All potassium supplements are used to deliver potassium for hypokalemic patients. (UPF 153 (Goldberg, Teagarden); UPF 154 (Bresnahan)). Products used for the same purpose meet *Brown Shoe. See United States v. Consolidated. Foods Corp*., 455 F. Supp. 108, 125 (E.D. Pa. 1978). Doctors wrote two-thirds of potassium prescriptions in June 1997 for potassium products other than K-Dur 20. (CX 62 at 089327).

Patient Compliance. The assertion that K-Dur 20's formulation offers any superior patient compliance (CAB:74) was not factually supported. (IDF 47-48, 81-82, 84; 89-90). Bresnahan conceded that K-Dur 20 had significant patient compliance issues. (UPF 163). Bresnahan had ignored marketing documents discussing Schering's compliance problems, including the tablet's large size, which was hard to swallow. (UPF 161, 163; CX 18 at SP 2300039, SP 2300045 (recognizing "low patient compliance/persistency"); CX 20 at SP 4040-41 (K-Dur 20 compliance a "challenge" "only 22% of patient retention" in a year); CX 746 at SP 2300378 (dissatisfaction with K-Dur 20 "high"; "rough finish of the tablet which makes it difficult to swallow")). Various potassium products were not "different clinically." (Bresnahan 8143).[11]

[11] The claim that K-Dur 20 created less gastrointestinal (GI) upset is false. (IDF 47). The FDA does not permit such a claim to be made by Schering, as the Patient Package Insert demonstrates. (Bresnahan 873-74).

Overall, Schering lamented that doctors remained unconvinced that K-Dur 20's dosage was a unique feature: "Few of the physicians reported that K-DUR is the only potassium supplement that has 20 mEqs of potassium." (CX 746 at SP 2300376 (emphasis supplied); Bresnahan 722-24).

c. Unique Production Facilities

Bresnahan conceded that the K-Dur 10 and 20 were produced in the same manufacturing plant. (IDF 85).

d. Distinct Customers

No distinct class of customers prefers K-Dur 20. (Bresnahan 1271; IDF 87; IDF 88 (Dritsas: "I've never heard of any special [customer] group that needs a special kind of potassium."); UPTB 80-81 **(**collecting citations); Bresnahan 707 (no K-Dur-only sub-class of patients)).

e. Distinct Prices

i) No Proof At Trial That K-Dur 20 Was Priced Supracompetitively

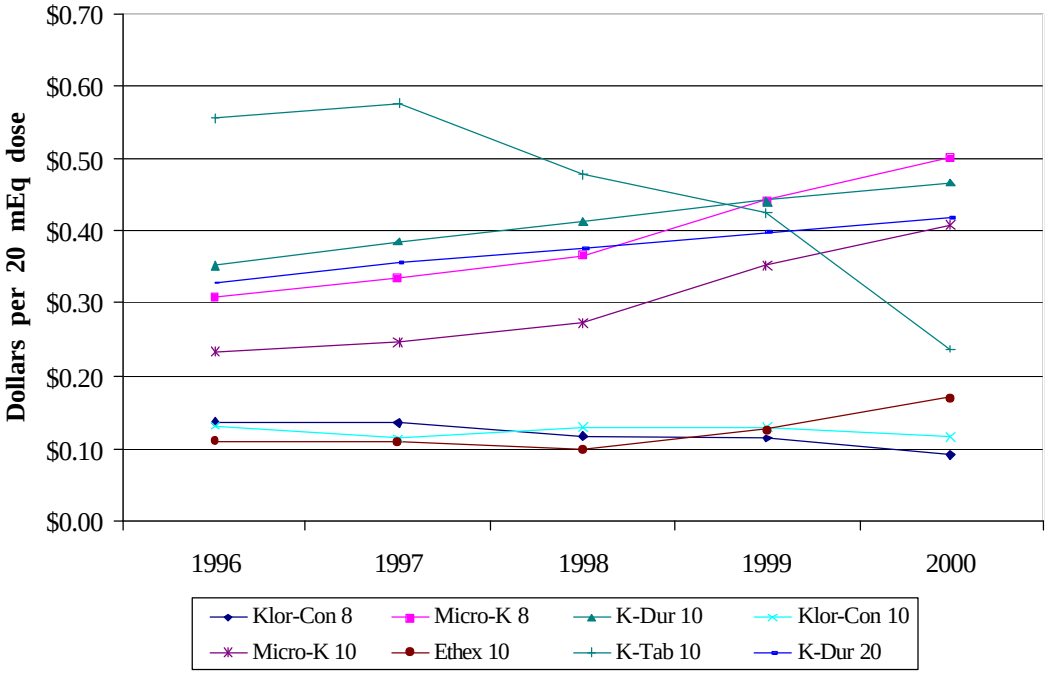
Complaint Counsel advanced no testimony that K-Dur 20 was priced supracompetitively — that is, above other forms of potassium, branded or unbranded. Amazingly, Complaint Counsel never asked its own customer witnesses (Teagarden or Goldberg) whether K-Dur 20 was priced higher than competing potassium.

Teagarden testified on cross that K-Dur 20 had the same price as Micro K. (Teagarden 217-18). Bresnahan testified that K-Dur 20 was priced at a level "comparable" to other potassium. (IDF 89). Abundant record evidence demonstrated that K-Dur 20 did not have a distinct price (IDF 89-103). Upsher-Smith's marketing personnel considered K-Dur 20 "[p]riced competitively." (CX 740).

Complaint Counsel's pricing case reduces to a single footnote, selectively quoting from a Schering marketing document regarding a "30% price advantage" between K-Dur 20 and certain generics. (CAB:51, n.51). They fail to quote the remainder of the same paragraph: "Generic competition continues to grow at the expense of K-Dur 20." (CX 18 at 2300039, 45, 47; CX 20 at 004040). This demonstrates cross-elasticity of demand between unbranded generics and K-Dur 20. (IDF 110). The growth of generic competition throughout this period is dramatically demonstrated by Figure 7 showing generic potassium. (CAB:53). And the "30%" quote is silent as to branded potassium such as Ethex or Micro-K.

K-Dur 20 did not have a supracompetitive price, relative to other potassium products. Addanki, who studied IMS pricing data, presented the only comparative pricing analysis. (SPX 2068; SPX 2069; Addanki 5741). From 1996 to 2000, at no point was K-Dur 20 the highest priced potassium; other brands were higher. (IDF 111; SPX 2069). In 1997, Addanki found that K-Tab 10 was the most expensive potassium supplement. (*Id.*; SPX 2068). Nor was K-Dur 20 the priciest potassium in other years: K-Tab 10 (1998); Micro-K 8 (1999) and Micro-K 8 (2000). (SPX 2069; Addanki 5743). Moreover, per equivalent dose K-Dur 10 was priced above K-Dur 20 at all relevant times. (SPX 2068).

Other KCl supplements were priced higher than K-Dur 20 between 1996 and 2000



Source: IMS Health, 2001.

SPX -2068

In fact, Addanki's analysis is conservative. K-Dur 20 was subject to millions of dollars of price-discounts, promotions and rebates. **(**IDF 114-115, 409-413). When Dritsas began marketing M20, he learned that K-Dur 20 was priced "like a generic." **(**Dritsas 4904-4905; SPX 2068; 2069).[12]

Complaint Counsel make much of K-Dur 20's pricing having increased over time (CAB:5). But branded potassium products were also increasing price over this same time period. Addanki 6203-04 (rapid price increases between 1996 and 2000 for K-Dur 10, Micro K, and

[12] Calculations made previously by Upsher-Smith based on average selling price, did not include any of these rebates that Schering was paying. (Dritsas 4743).

Ethex 10 — in some cases, even faster than K-Dur 20's price increase). Thus, they have no evidence of a supracompetitive price being charged by Schering for K-Dur 20.

ii) Complaint Counsel's Sole Witness Did No Pricing Work

Bresnahan did no work to opine about whether the K-Dur 20 pricing was above that of potassium competitors. (IDF 112). Complaint Counsel concede that "Professor Bresnahan did not employ certain methodologies — including price tests, econometric studies, and the measurement of price elasticity — to reach his conclusions." (CAB:75). They argue that Bresnahan **"**concluded it was not necessary to employ" basic methodologies for determining market power and imply that "the choice of methodology is a function of 'the available body of facts and information.'" (CAB:75**)**.

In short, Bresnahan made no pricing study comparing K-Dur 20 to other potassium products (IDF 90) and Complaint Counsel make no attempt to describe the work that he did. Bresnahan was unable to study pricing because he did not have access to a pricing data set for K-Dur 20 or other potassium products. (IDF 90), and did not ask any other firm's pricing. (Bresnahan 867 (neglected to ask Complaint Counsel to subpoena pricing data sets from other potassium firms)). By contrast, Dr. Addanki did use IMS data to present relative pricing comparisons.

Bresnahan also:

- did not study the effects of M20 entry on K-Dur 20 pricing (IDF 93);
- did no study of rebates (IDF 117, 424);
- conducted no analysis of physician or customer substitution (Bresnahan 755);
- did no study of Schering's marketing on the total market demand for potassium (IDF 425);

- did no study of first-mover effects within the potassium marketplace (IDF 426);
- did no analysis of K-Dur 20's promotional expenses (IDF 427);
- conducted no analysis of other potassium firm's promotional spending (IDF 429); and
- conducted no surveys or interviews of doctors, HMOs, patients or pharmacists (Bresnahan 690-92).

Further weakening any reliance on Figure 1 or 2 is that Bresnahan made no study of Schering's costs. Specifically, Bresnahan:

- Made no comparisons of cost over time: "I didn't make any analysis of costs changing over time at all . . . I didn't make any time series comparisons of costs at all." (Bresnahan 8148).
- Did not study raw material costs for K-Dur 20. (*Id.*).
- Did not examine the cost of capital or production solvents. (Bresnahan 8148-49).
- Did not examine labor costs or distribution costs of distribution. (Bresnahan 8149).
- Did not compare or changes in costs between K-Dur 20 and other potassium products. (Bresnahan 8149-50).

Concerned about the absence of evidence of pricing Complaint Counsel performed new calculations post-trial in proposed Table 1 (discussing only 10 products), which was stricken. Bresnahan conducted no statistical analysis on relative pricing of potassium done statistically. (IDF 112, 419-422).

Plaintiff has the burden of proving supracompetitive pricing to prove market power or monopoly power. *See R. J. Reynolds Tobacco Co. v. Philip Morris Inc.*, 199 F. Supp.2d 362, 381-3 (M.D.N.C. 2002) (plaintiff must "put [] forth evidence of restricted output and supracompetitive prices" to prove market power) (citations omitted). There is no record evidence that Schering charged supracompetitive prices.

The failure to present rigorous pricing evidence is fatal to Complaint Counsel's proposed product market. *See Bailey v. Allgas, Inc.*, 284 F.3d 1237, 1247 (11th Cir. 2002) (rejecting plaintiff's market because expert failed to determine cross-elasticity of demand between competing products); *Alcatel USA, Inc., v. DGI Techns, Inc.*, 166 F.3d 772, 783 (5th Cir. 1999) (rejecting market because plaintiffs "never compared [defendant's] prices to its competitors' prices" and "did not prove that [defendant's] customers face substantial information and switching costs"); *Murrow Furniture*, 889 F.2d at 528 (rejecting economist's unsupported assertion of high-end furniture market; "Courts have repeatedly rejected efforts to define markets by price variances or product quality variances. Such distinctions are economically meaningless where the differences are actually a *spectrum* of price and quality differences") (citation omitted); *H.J., Inc. v. Int'l Tel. & Tel. Corp.*, 867 F.2d 1531, 1538 (8th Cir. 1989) (rejecting plaintiff's market where plaintiff's expert failed to conduct any relative cost comparison to prove the alleged monopolist had the ability to control prices); *Geneva Pharms.*, 201 F. Supp. 2d at 270 (rejecting plaintiff's product market of generic warfarin drug due in part to failure "to conduct a formal test regarding the degree of purported differential impact that Apothecon's entry had on the price of Barr's warfarin").[13]

iii) Cases Support *Brown Shoe* Analysis

Complaint Counsel's suggestion that the *Brown Shoe* indicia are irrelevant to the evaluation of their K-Dur-only market **(**CAB:73**)** is incorrect. They rely on cases using *Brown Shoe* indicia. (ID 90; *see FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1075-80 (D.D.C. 1997) (*Brown*

[13] *See also SMS Sys. Maint. Servs., Inc., v. Digital Equip. Corp.*, 188 F.3d 11, 25 (1st Cir. 1999) (rejecting market because expert "did not conduct a customer satisfaction survey, but based his opinion on his interpretation of certain internal . . . documents"), *cert. denied*, 528 U.S. 1188 (2000); *United States v. Engelhard Corp.*, 126 F.3d 1302, 1306 (11th Cir. 1997) (government did not put forth the necessary pricing data to prove a relevant market).

Shoe "practical indicia" included characteristics of office superstores, industry recognition, cross-elasticity of demand); *FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 45 (D.D.C. 1998) (unique features of the drug wholesaling, including specialized customers such as hospitals dependent on wholesalers); *In re Coca-Cola Bottling Co.*, 118 F.T.C. 452, 540, 546, 553-54, 573 (1994) (citing *Brown Shoe*; "different market channels"; market participant, industry, customer opinion); *In re Olin Corp.*, 113 F.T.C. 400, 603 (1990) (separate market with differences in "physical and technical characteristics," chemical concentrations, shelf life, customers)).

Complaint Counsel cite (CAB:74) *Smith-Kline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1978), which found cephalosporin antibiotics to be distinct from other antibiotics. But the court used *Brown Shoe* indicia, finding the drugs were used for specialized patients. (*Id.* at 1063; ID 90). This cannot be said of K-Dur 20 where products are "therapeutically equivalent," and there are no special K-Dur-only patients. (IDF 39, 41, 43-55, 87-88; Freese 4952; USX 410 at 190292).

The Commission did not find a separate product market for a branded drug in *In re Warner-Lambert Co.*, 87 F.T.C. 812, 877 (1977). The Commission found that branded and unbranded thyroid drugs were in the same product market despite the "lack of price elasticity between branded and unbranded products" for a number of reasons — including the fact that Respondent's documents, as here, treated products as a single market. (*Id*; (ID at 89-90)). The court in *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, recently followed *Warner-Lambert*, ruling that a plaintiff's proposed generics-only submarket failed because *Brown Shoe* practical indicia were not proved, when plaintiff merely relied on evidence of price inelasticity. 201 F. Supp. 2d 236, 270 (S.D.N.Y. 2002) (dismissing case for failure to establish a submarket consisting solely of generic warfarin).

f. Sensitivity To Price Changes

Complaint Counsel introduced no evidence on K-Dur 20's price sensitivity, because their expert had no pricing data. (IDF 90; IDF 92, 420 (Bresnahan conducted no price sensitivity analysis), 113 and 422 (no cross-elasticity of demand), 421 (no comparative econometric analysis)).

The failure to establish this basic evidence is fatal to Complaint Counsel's claims. *See, e.g., Lantec, Inc. v. Novell, Inc.*, 146 F. Supp.2d 1140, 1148-49 (D. Utah 2001) (dismissing Section 1 and 2 claims "[b]ecause there is no evidence on the costs of the various products or of how the consumer would react to a price increase in such costs, there is no evidence of price sensitivity" under *Brown Shoe*; plaintiffs' "evidence is insufficient to establish their definition of the relevant market"), *aff'd*, 2002 WL 31081822 (10th Cir. Sept. 19, 2002).

The record shows not only price sensitivity, but also K-Dur 20 losing market share to other potassium products. (IDF 106). Bresnahan conceded that Schering was losing sales of K-Dur 20 to generic potassium. (Bresnahan 829; CX 746 at 2300370, CX 18 at 2300039, 45, 47 and CX 20 at 004034-35, 004040). Bresnahan conceded that customers were switching to alternatives based on price. (Bresnahan 853 (consumer substitution of Klor-Con 8 and 10 for K-Dur 20), 751-52 (K-Dur 20's price grew 10-mEq generics sales)).

Price-Cutting Drove Market Share Gains. Pricing sensitivity was demonstrated by a shift in sales to Apothecon. (IDF 107). After Apothecon entered in 1996, it began discounting potassium supplement pricing leading to increased sales. (IDF 107; Addanki 6181 ("there was a lot of price competition in the market"); USX 1551). Upsher-Smith's marketing personnel noted the market was becoming more price sensitive:

> Recently, Apothecon entered the market with a generic to their own brand Klotrix. This entry, along with a dramatic change in their unit trend in 95, reiterates ***the fact that this market is becoming increasingly price sensitive.***

(CX 50 at 13530; Addanki 6182 (emphasis supplied)).[14]

Figure 7 (CAB:53) demonstrates growing price sensitivity. Generic potassium sales rose 60% from 1994 to 2000 — from 10 million total prescriptions (TRX) to 16 million.

Complaint Counsel hide behind Figure 7 in an attempt to avoid Schering documents. The contemporaneous business documents show Schering was worried about generic competition: "Generic competition continues to grow at the expense of K-Dur 20." (CX 18 at SP2300039).[15] Schering's marketing strategy was designed to mount "a strong effort to grab share from generics." *Id*.

Customer Sensitivity to Rebates. K-Dur's sales grew due to advertising. (IDF 411; IDF 412; ID 117). The potassium market is a "promotion-sensitive market[]" and that Schering invested "heavily in field force effort" to promote K-Dur. (ID 117 (Russo); Bresnahan 651)). Schering invested millions in free goods, rebates, advertising, discounting, marketing, and promotion. (Addanki 5724-25; Bresnahan 733-34). Bresnahan did not evaluate any of these. (IDF 117, 423-25, 427; Bresnahan 651-52, 735, 763, 1176). These expenditures demonstrate the price sensitivity of purchasers. (ID 95).

Schering outspent all competitors combined by more than a ***four-to-one*** margin on advertising, and outspent Upsher-Smith ***100 to 1***. (IDF 411 (emphasis supplied) (Bresnahan)). Schering specifically advertised against 10-mEq potassium. (IDF 79-80; CX 18 at SP 230057 ("20 Versus 10" Mail Series)).

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[14] Price sensitivity appears throughout Upsher-Smith's marketing documents. (USX 425 at 1002952 (sales of Apothecon's potassium products rose 487%); USX 380 at 142328 (Apothecon increased unit sales by 8.7%)).

[15] Figure 7 is a chart presented after the close of the record, with no witness, no methodology, no description of which products are in the generic or branded categories, no scale (apparently TRX), and no reference to record evidence. Bresnahan never sponsored it.

From October 1, 1997 to June 30, 2001, Schering spent ***$136 million in rebates*** paid to K-Dur customers. (IDF 115; CX 695 at SP020698-702; Addanki 6172-73). Schering spent more than $30 million annually on rebates from 1998 through 2000. (IDF 114; Addanki 6172-73). Rebates reduced the net price that Schering's customers paid; Schering "[was] competing on price through rebates." (IDF 116, 111).

g. Specialized Vendors

K-Dur 20 is not distributed by specialized vendors that differ from the vendors for other potassium products. The unrebutted evidence is that K-Dur 20 is dispensed at pharmacies, like other potassium products (IDF 118; *see* Bresnahan 696-97 (dispensed at pharmacies)).

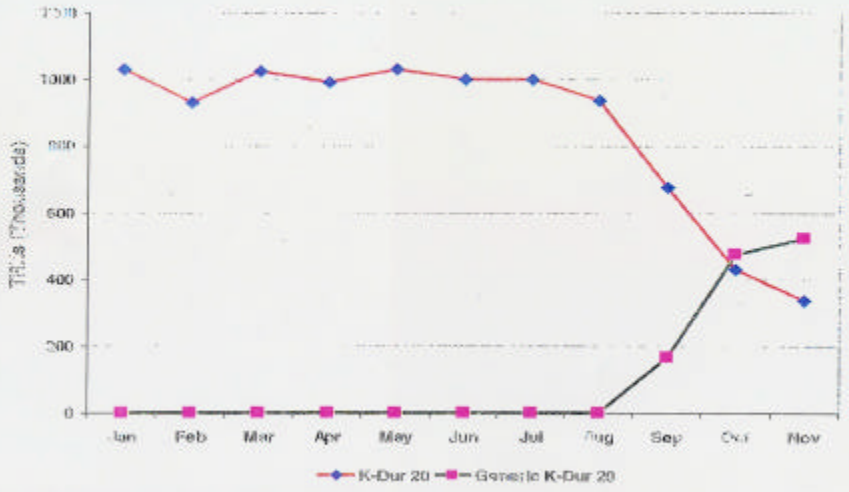
3. The 2001 Reduction In K-Dur 20 Sales Reflects Mandatory Substitution Laws Not Monopoly Power

Complaint Counsel assert that the post-September 1, 2001 decline in the sales of K-Dur 20 proves K-Dur 20 is a monopoly. (CAB:72). This ignores the role of government fiat. Many states force pharmacists to dispense AB-rated generics. (CPF 37 (collecting mandatory state substitution laws); IDF 100). These laws compel substitution for the branded drug, regardless of whether it is an antitrust monopoly. Complaint Counsel concede that substitution laws are the ***main reason*** for branded sales decline when an AB-generic is sold:

> The ***main reason*** a generic drug has such a dramatic effect on the sales and the market price paid for the drug product is ***due to state generic drug substitution laws***. Most states have laws that allow pharmacists to automatically substitute a generic drug for its branded equivalent without obtaining prior approval from the prescribing physician.

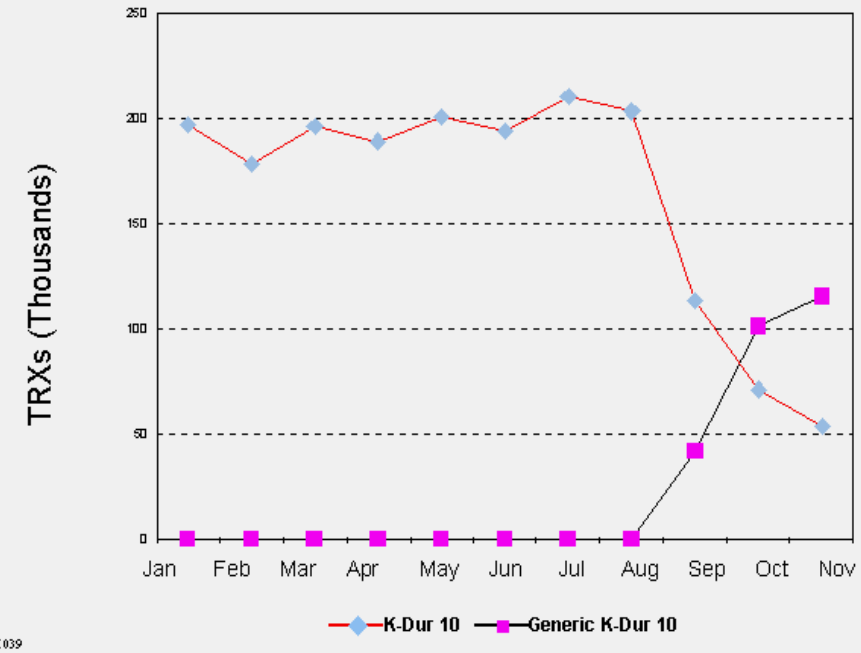
(CPTB 92 (emphasis supplied)). Due to mandatory state substitution laws the sales charts for K-Dur 20 and K-Dur 10 (not a monopoly product, IDF 102-03) are identical:

Estimated TRXs for Selected Potassium Chloride Products
January 2001 – November 2001



CX 1586

Estimated TRXs for Selected Potassium Chloride Products
January 2001 – November 2001



D-USX 039

USX 1557

Complaint Counsel recast this argument as "switching costs" (CAB:74-75) but to no avail. They contended that there is no "switching cost" at the pharmacy level because mandatory state laws force automatic substitution to AB-generics. But Bresnahan testified that demand for potassium begins at the point of prescription when patients visit their doctor, not the pharmacist's counter. (IDF 38, Bresnahan 696). There are no switching costs at the doctor's office. **(**Bresnahan 696-97 ("there is no switching cost at that stage")).[16]

At the point of the prescription pad, doctors can prescribe any potassium — K-Dur 20, a branded potassium, or simply "KCl." Sixty percent of potassium prescriptions are written "open" meaning that the doctor writes "KCl" on the prescription, without specifying any brand, and pharmacists decide how to fill the prescription. (Dritsas 4750-51). There are no switching costs for these prescriptions. (Addanki 5702-03).

Schering's documents exhibit genuine concern about pharmacy-based switching eroding K-Dur 20 sales. Schering's 1997 K-Dur Marketing Plan concluded that it must

> **Develop and implement trade based programs to discourage switching.** Programs that reward market share performance can discourage switching at the pharmacy level.

CX 18 at SP2300048 (emphasis in original).

Further, K-Dur 10 too could be said to have this "switching cost" prior to September 2001 by this logic. But that did not make K-Dur 10 a monopoly.[17]

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[16] A prescription for "K-Dur 20" can be switched when the pharmacist calls the doctor's office. (Freese 4956-57; Addanki 5703). The cost of these calls is trivial. (Bresnahan 698-99). Pharmacists call doctors frequently to switch prescriptions, (Addanki 5703) and it is part of the service that pharmacies provide their customers. (Addanki 5702-03; 6196-97).

[17] Upsher-Smith marketed Klor-Con 10 directly to pharmacists, and these efforts led to continuous sales growth throughout the 1990s. (Dritsas 4617, 4622-4623). Ironically, the IMS substitution data Complaint Counsel rely on, CX 43, accounts for less than one-third of the 8 million K-Dur 20 prescriptions, and the survey data are ambiguous. (Addanki 6208).

4. There Are Not "Multiple Monopolists" Selling Potassium

Complaint Counsel apparently suggest that there are multiple monopolists selling potassium — as if each potassium brand were a monopolist. They essentially assert that Ethex behaved monopolistically: Ethex "raised prices on both the brand and generic without losing sales." (CAB:52-53). Such a concept puts pressure on language, with ***multiple monopolists*** competing for potassium sales, and Bresnahan did not conclude Ethex was another monopolist. (Bresnahan 8147: Addanki 6204).

Similarly, K-Dur 10's prices rose every year **(**CX 49 SP049048-049049**)** and its sales rose. (CX 62-65.) Based on the logic of Figure 1, K-Dur 10 is a potassium monopoly — an erroneous conclusion. (IDF 102 (Bresnahan: K-Dur10 not a monopoly)). Micro-K raised its price 61% for Micro-K 8 and 78% for Micro-K 10 between 1996 and 2000; again, these rapid price increases do not permit an inference of monopoly products. (Addanki 6203-04).[18]

Courts have rarely found such single-product product markets and repeatedly have held that the "monopoly" a firm has in its own brand is not antitrust monopoly. *See Brown Shoe,* 370 U.S. at 368 n.3 ("one can theorize that we have monopolistic competition in every nonstandardized commodity with each manufacturer having power over the price and production of his own product") (citation omitted); *see also* UPTB 67-68 (collecting cases).

5. The "Cellophane Fallacy" Is Inapplicable

Faced with overwhelming evidence of a broad potassium market, Complaint Counsel invoked the cellophane fallacy. Bresnahan's cellophane testimony was based on the Carlton and

[18] Nor does Figure 2 demonstrate any monopoly power. (CAB:6). Figure 2 (not used with Bresnahan) merely shows that as K-Dur 20's sales dollars rose, its margin dollars rose. This is true in any business or industry. Even at constant profit margin rates, the margin dollars rise as sales dollars rise.

Perloff textbook. (Bresnahan 8126). But Bresnahan followed none of the textbook's methods for determining the relevant market. (Bresnahan 8129-30) (textbook methods include "interview[ing] producers in the industry;" "a reasonable first step in defining economic markets is to examine the price correlations (a statistical measure of how closely prices move together) among different products."); (IDF 113, 422; Bresnahan 8129; 8130-34; Bresnahan 690 (no statistical comparison of K-Dur 20 with other potassium products; no regression analysis; no econometric analysis)).

The Second Circuit rejected the government's invocation of the cellophane fallacy, noting that the fallacy is inapplicable where the products are "excellent substitutes" for each other. *United States v. Eastman Kodak Co.*, 63 F.3d 95, 105 (2d Cir. 1995). ("This case, however, does not involve a comparison of two highly-differentiated products like cellophane and wax paper . . . .[T]he film produced by Kodak's competitors is . . . an excellent substitute"). Here, the products are "therapeutically equivalent." (IDF 39-55; Russo 3412-13). Addanki's pricing work addressed the cellophane fallacy head-on. (Addanki 5960).

B. Schering's 25% Increase In Output Contradicts A Monopoly

Schering's K-Dur 20 output rose 25% between 1997 and 2001, according to Bresnahan. *See* Bresnahan 8181 ("output measured in prescriptions had gone up by a quarter"); CX 1765; Bresnahan 8181 (K-Dur 20 total prescriptions rose from 800,000 to 1,000,000 between 1997 and 2001). K-Dur 20 prescriptions "increased continually" between 1994 and 2001. (CAB:49-50). Schering-Plough took "every opportunity that it could to expand its sales"; its promotion and advertising stimulated demand. (Addanki 5745).

Rising output is inconsistent with the existence of monopoly. (Addanki 5745-46). *See A.A. Poultry Farms, Inc. v. Rose Acre Farms, Inc.*, 881 F.2d 1396, 1403 (7th Cir. 1989) (court affirming motion for judgment notwithstanding jury verdict for defendants finding that

"monopoly pricing comes from restrictions in output" while persistent entry and expansion ensures no monopoly power or recoupment). Rising output is also inconsistent with supracompetitive pricing. *See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 233 (1993) ("Supracompetitive pricing entails a restriction in output."); *R.J. Reynolds Tobacco Co.*, 199 F. Supp. 2d at 381 (failure to prove restricted output fatal to plaintiffs' supracompetitive price claim).

C. Schering's Market Share Was Insufficient To Establish Monopoly Or Market Power

1. K-Dur 20 Had Only 33% Market Share

Schering's market share — to be measured as of the Settlement according to Bresnahan — was only 33% of total prescriptions (TRX) in June 1997, according to IMS.[19] (IDF 402). IMS data is organized under potassium, 60110. (IDF 83). Bresnahan conceded that he never saw a document in which Schering executives believed that they had greater than 60% "market share" with the sale of K-Dur 20, as they themselves viewed the "market share." (Bresnahan 875-76).

Bresnahan did not consider Schering's business documents demonstrating that both of Schering's K-Dur drugs had a combined market share of approximately 38% of potassium prescriptions, while generic manufacturers had between 60-70% of the potassium chloride market. *See* Tr. 1277-79; 819; 710; 748-49. Similarly, Goldberg testified that K-Dur 10 and 20 combined represented only 30% of United Health Care's own potassium prescriptions as of August 2001. (Goldberg 163-64).

[19] Further evidence of a broader product market is that Schering combined K-Dur 10 and 20 into a single category "K-Dur". (IDF 60; CX 20 at SP 004034).

2. 33% Market Share Does Not Constitute Monopoly or Market Power

A 33% market share is insufficient as a matter of law to prove a monopoly. (ID 115 (collecting cases)). Courts require greater market share in order to establish monopoly power or that a firm is a "monopolist" — typically 70% market share or greater. (ID: 115 (collecting cases)); *United States v. Aluminum Co. of America*, 148 F.2d 416, 424 (2d Cir. 1945) (stating that "it is doubtful whether sixty or sixty-four percent would be enough; and certainly thirty-three percent is not.") (Hand, J.); (UPTB 96-97 (collecting cases)).

A 33% market share is insufficient to establish market power. *New York by Abrams v. Anheuser-Busch, Inc.*, 811 F. Supp. 848, 873 (E.D.N.Y. 1993) (defendant's "39% [market] share is below that which has been deemed sufficient to confer market power"; rejecting Section 1 claim); *id*. at 871-73 n.70 (collecting cases). *See also Acme Mkts. Inc. v. Wharton Hardware & Supply Corp*., 890 F. Supp. 1230, 1241-42 (D.N.J. 1995) (40% share insufficient); *Winter Hill Frozen Foods & Services, Inc. v. Haagen-Dazs Co.*, 691 F. Supp. 539, 547-548 (D. Mass. 1988) (43% share insufficient).[20]

D. Ease Of Entry and Expansion Defeat Monopoly Power

There is no evidence of barriers to entry into the potassium market or of Schering's ability to restrict other competitors' output. (IDF 408; ID 115). Ease of entry into the potassium market thwarts any inference of monopoly power. (ID 115); *see Am. Prof'l. Testing Serv., Inc. v. Harcourt Brace Jovanovich*, 108 F.3d 1147, 1154 (9th Cir. 1997) ("Even if [defendant] has a high market share, neither monopoly power nor a dangerous probability of achieving monopoly power can exist absent evidence of barriers to new entry or expansion"); *Concord Boat Corp. v.*

[20] Bresnahan's Test specifically employs a monopoly power threshold for reviewing settlement agreements. *See supra* Intro.

Brunswick Corp., 207 F.3d 1039, 1060 (8th Cir. 2000) (plaintiff "had to produce evidence to show that [defendant's] market share discount programs were an unreasonable contractual arrangement, based on . . . the erection of entry barriers"); *Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98, 112 (3d Cir. 1992) (although market share is significant, barriers to entry must be considered before finding monopoly).[21]

1. Bresnahan Conducted No Study Of Entry

Bresnahan did no work on ease of entry or barriers to entry. (IDF 405). Bresnahan did not study the examples of entry into the potassium market, how long entry took, or entry costs. (IDF 405, 431). Failure to study entry constitutes failure to prove product market. *Geneva Pharms.*, 201 F. Supp. 2d at 270 (rejecting plaintiff's product market because of failure "to conduct a formal test regarding the degree of purported differential impact that Apothecon's entry had on the price of Barr's warfarin").

2. Entry Into Potassium Occurred And Was Successful

Upsher-Smith spent less than $100,000 to enter the sale of potassium. (Dritsas 4631-32). After its entry, Upsher-Smith's Klor-Con wax-matrix line enjoyed "steady growth since launch and remained the dominant product for Upsher-Smith through 1997." (USX 643 at 16087; Dritsas 4725-26).

In 1996, five firms began selling potassium: Ethex, Apothecon, ESI Lederle, Medeva and Biocraft. (IDF 405-06; USX 626 at 15228 ("the focus has been on price with continued

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[21] Ease of entry precludes a finding of "market power" under a Section 1 Rule of Reason challenge. *See Carter v. Variflex, Inc.*, 101 F. Supp.2d 1261, 1267-68 (C.D. Cal. 2000) ("Even where the defendant's market share is substantial, the absence of barriers to entry by new firms or expansion by existing firms can deprive new firms or expansion by existing firms can deprive a defendant of market power;" rejecting Section 1 challenge) (citations omitted); *see* UPTB at 102 n.19 (collecting cases).

growth from generics such as Ethex and new entries from Apothecon, ESI Lederle, Medeva and Biocraft in 1996.")). Firms could enter without a field sales force. (Dritsas 4726). The fact that 25 firms sold potassium in 1997 attests to frequent entry having occurred. (IDF 406; ID 115; *see, e.g., Am. Prof. Testing Service, Inc.*, 108 F.3d at 1154 (existence of 29 competitors suggests "any barriers to entry may not be that significant")).

Recent entry demonstrates that entry barriers are low, and that Schering lacks market power. *See Barr Labs., Inc.*, 978 F.2d at 112-14 (recent entry "supports our conclusion that [drug manufacturer's] allegations of high barriers to entry pose no obstacle to the conclusion that a competitive market existed here"; rejecting FDA approval as a barrier where firms purchased and resold drugs from manufacturers); *R.J. Reynolds Tobacco Co.*, 199 F. Supp. 2d at 383 ("Unrebutted evidence that actual competitors have entered the market is a strong indicator that [the defendant] lacks market power") (quoting *Anti-Monopoly, Inc. v. Hasbro, Inc.*, 958 F. Supp. 895, 904 (S.D.N.Y. 1997)).[22]

The evidence also established that potassium producers in the market could expand output. (IDF 407). In 1999, Ethex and Major, two existing potassium producers, expanded sales through low prices and intensified marketing. (IDF 407). When K-Dur 20 production fell in the Summer of 2001 due to Schering's regulatory compliance issues, Upsher-Smith filled the void

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[22] Entry does not depend on FDA approval. (Dritsas 4725-26; Addanki 5722). Firms have entered potassium through contract manufacturing arrangements with FDA-approved firms. (Dritsas 4725-26 ("It's relatively easy to enter the potassium market . . . we simply contacted someone to make it for us, and we were on the market."). Similarly, Qualitest entered and became a substantial player overnight by purchasing M20. (Dritsas 4676-77; *see Barr Labs., Inc.*, 978 F.2d at 113-14 (entry through contract manufacturing arrangement important because "pharmaceutical companies compete for sales with the manufacturers from which they buy their products;" recent entry demonstrated that even high entry barriers entry did not preclude entry and expansion)).

by selling its wax matrix Klor Con 8 and 10 tablets, demonstrating the ease with which supply can expand to meet new demand. (Dritsas 4825).

Because Bresnahan did no entry work, after trial Complaint Counsel drafted Figure 1 and Figure 6 as a substitute for an entry case. They were not presented to Judge Chappell; Bresnahan chose not to defend either Figure 1 or 6. The lack of relative-pricing data means that these figures cannot demonstrate supracompetitive pricing, because no other firm's prices appear. *See Levine v. Central Fla. Med. Affiliates, Inc.*, 72 F.3d 1538, 1551 (11th Cir. 1996) (finding evidence of increased prices insufficient to show harm to competition without information on prices charged by competitors); *Godix Equip. Export Corp. v. Caterpiller, Inc.*, 948 F. Supp. 1570, 1582 (S.D. Fla. 1996) (finding no antitrust violation in part because "[p]laintiffs merely presented evidence of rising prices without discussing the increased prices in relation to the rest of the market.").[23]

As noted above, Schering outspent all of its rivals driving sales and increasing output. **(**IDF 411). Complaint Counsel have no analysis studying the impact of promotion. (IDF 93; *see* Bresnahan 1274). Other products also raised their prices in this time period. See SPX 2068 discussion supra.

Similarly, the ability of existing firms to expand output will constrain a would-be monopolist's pricing. (IDF 407). Potassium producers have expanded output during the 1997-2001 time period, as Apothecon readily did. (IDF 407).

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[23] Further, the choppiness in the Figure 1 K-Dur 20 sales figures which even Bresnahan noted (Bresnahan 8181) — with 5%-10% or greater fluctuations — remain unexamined and unexplained by Bresnahan (e.g., Figure 1 saw-tooth gaps in sales in Spring 1997 and Spring 1998). The record evidence is clear that new entrants made an impact in the market not just initially, but over time. (USX 425 at 1002952; USX 380 at 142328).

E. No Direct Effects Were Proved Under *Indiana Federation*

Faced with company documents showing a broad potassium market, Complaint Counsel retreated, eschewing proof of product market. They asserted they would prove direct market effects of "increased prices ***and reduced output***" under *Indiana Federation of Dentists.* (CAB:63). *See, e.g., Rebel Oil Co. Inc. v. Atl. Richfield Co.,* 51 F.3d 1421, 1434 (9th Cir. 1995). (*Indiana Federation* requires "restricted output ***and*** supracompetitive prices."). Complaint Counsel proved neither: Bresnahan did no comparative pricing analysis (ID 91; IDF 90, 92, 112-13, 420-21, 423, 427-28), and Schering's output rose at all relevant times. (CAB:49-50; IDF 409-13).[24]

IV. THERE WAS NO PROOF OF OTHER ANTICOMPETITIVE EFFECTS

In a scant three paragraphs (CAB:63-65), Complaint Counsel half-heartedly urge two other anticompetitive effects: (1) that the Settlement Agreement, together with Upsher-Smith's alleged delay, "created an obstacle to entry by other generic competitors" (CAB:63-64); and (2) that the Agreement contained an unlawful ancillary restraint (CAB:64-65). At trial, Complaint Counsel conceded that "the complaint does not plead either matter as an independent violation." (CC-UMD at 7 n.20). Judge Chappell properly found that neither raised competitive concerns. (ID 112-14).

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[24] Similarly, Complaint Counsel's sinister view of two Schering sales projections (Figure 4 (CAB:13)) does not account for the record evidence. Not only did Complaint Counsel avoid confronting any Schering employee with Figure 4, but they assume causation simply because the second projection (Nov. 1997) followed the settlement. Schering dramatically revised upwards its sales projections for other cardiovascular drugs. (Compare CX 118 at SP2300219 with CX 750 at SP2300307aa (projections for Imdur and Nitrodue, two products unaffected by the Schering/Upsher-Smith setlement, rose comparably over June 1997 projections)).

A. No Competitor Was Blocked By 180-Day Exclusivity

Once again, this case is unique. No evidence was introduced that Schering or Upsher-Smith ever discussed or ever intended to block or delay other entrants via the Agreement, or that "any competitor [was actually] blocked from entry into the market because of Upsher-Smith's 180[-day] exclusivity." (IDF 395-98).

1. No Generic Firm Was Blocked By Upsher-Smith's Exclusivity

Complaint Counsel never proved that Upsher-Smith's Hatch-Waxman exclusivity blocked the entry of any other generic. According to Complaint Counsel's witness from Andrx — the only generic firm alleged to have been blocked (Compl. ¶¶61-62) — {

.} (Rosenthal 1591, 1553, 1734-35 (*in camera*)). {

}.

(Rosenthal 1727-28; USX 67 {

}); Rosenthal 1728-31; (USX 66 ({

}); Rosenthal 1730-33;

(USX 704; Rosenthal 1734 (*in camera*)). ({

}. ((Rosenthal 1735; IDF 395 ({ })) (*in camera*) (emphasis supplied)).

Complaint Counsel never even claimed that any other firm was blocked by Upsher-Smith's exclusivity. Bresnahan testified that he did not know of ***any*** generic blocked in fact by Upsher-Smith's 180-day exclusivity. (Bresnahan 912; IDF 398 (no firm blocked)).

2. The Parties Did Not Discuss Hatch-Waxman Act's 180-Day Exclusivity

Complaint Counsel asserted that Respondents conspired to exclude other entrants via the Settlement. (Compl. ¶47). But the parties never discussed 180-day exclusivity: "It was never raised at any time by any person on either side of the negotiating table at any meeting." (Troup 5492-93; IDF 399; *see also* John Hoffman 3550-51). Complaint Counsel introduced no evidence to rebut this testimony, and the documents confirm the lack of discussion. Bresnahan's review of the documents revealed no company documents referring to 180-day exclusivity. (Bresnahan 913, 915-17).

Consequently, the Agreement never mentions the 180-day exclusivity. (Troup 5493 (CX 348)). Upsher-Smith remained free to transfer or waive its exclusivity. This distinguishes the Agreement from the agreements in the Cardizem and Hytrin cases.[25]

3. The 180-Days Was Not Exclusive

Bresnahan acknowledged that during Upsher-Smith's exclusivity period, ***three AB-rated*** generics were marketed, by Upsher-Smith, Warrick (Schering's generic division) and Qualitest. (Bresnahan 929). By December 2001, ***20 percent*** of M20 production was sold to Qualitest for remarketing. (Dritsas 4676-77). Qualitest opened new sales channels and drove scale economies. (Dritsas 4642-43).

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[25] FTC, Analysis to Aid Public Comment, *In the Matter of Abbott Labs.* ("Hytrin"), May 26, 2000 at *2 (contract refers to 180-days provision: "Geneva also agreed — at Abbott's insistence — not to transfer, assign, or relinquish its 180-day exclusivity right."); FTC, Analysis to Aid Public Comment, *In the Matter of Hoechst Marion Roussel, Inc.*, ("Cardizem"), April 2, 2001 at *3 ("Andrx agreed not . . . . "to relinquish or otherwise compromise any right accruing under its ANDA, including its 180-day exclusivity right").

4. The Tremendous Regulatory Uncertainty Prevailed

According to Joel Hoffman, a 38-year FDA-law specialist and Complaint Counsel's Hatch-Waxman expert, in June 1997 there was "substantial uncertainty" regarding Upsher-Smith's eligibility for 180-day exclusivity. (Joel Hoffman 2193). Had Upsher-Smith retained Joel Hoffman that month, he would have had "***no idea***" as to the settlement's effect on exclusivity. (Joel Hoffman 2322-23 (emphasis supplied)).

In June 1997 Troup "was unclear in the extreme" regarding exclusivity (Troup 5491), and his "best guess" was that he had "given that up by reaching a settlement." (*Id*.) Similarly, Dritsas believed Upsher-Smith had "lost" exclusivity by settling. (Dritsas 4666). This is one reason exclusivity never came up in the negotiations with Schering.

B. The Agreement Contained No Unlawful Ancillary Restraint

Bresnahan could not support Complaint Counsel's assertion that Paragraph 3 — prohibiting Upsher-Smith from marketing "any other sustained release microencapsulated potassium chloride tablet prior to September 1, 2001" (CX 348 at USL 03186) — restrained competition.

Bresnahan did not consult a biochemist, pharmacologist or patent expert to determine whether it was physically possible to develop another generic sustained-release microencapsulated potassium chloride product without infringing the '743 patent. (Bresnahan 185). Bresnahan did not examine Upsher-Smith's product pipeline for 1997 to 2001. (Bresnahan 984). Bresnahan saw no evidence that Upsher-Smith believed Paragraph 3 applied to any product beyond M20. (Bresnahan 984, 987; *see also* IDF 169).

Schering originally drafted language preventing Upsher-Smith from marketing "any other 20 mEq potassium chloride product," which would have blocked Upsher-Smith's 20-mEq potassium powder. (USX 105 at FitzCella0146; USX 630 at USL1533). Troup and Cannella

negotiated the clause to cover only "sustained release microencapsulated potassium chloride tablet[s]" (CX 348 at USL03186; Cannella 3848-49). The change preserved Upsher-Smith's ability to sell its wax-matrix Klor-Con potassium. (Troup 5469-70; IDF 167). The parties believed that Paragraph 3 was limited to products using the microencapsulation process covered by the '743 patent. (USX 732 at SP 1200203; Dritsas 4836; Troup 5470).

Economist Kerr (a patent-litigation expert) testified that language such as that found in Paragraph 3 "is an essential feature in many patent agreements." (Kerr 6338). For patent settlements to work, they must specify the products covered by the settlement. (Kerr 6334, 6336, 6337-39). This specificity is necessary to: (i) limit the alleged infringer's ability to circumvent the settlement (Kerr 6338-39); and (ii) avoid a general reference to "infringing" products because parties typically disagree about what constitutes an infringing product (Kerr 6339) — leading to renewed litigation with its attendant costs. (ID 112-13).

Ancillary restraints are entirely permissible if "reasonably necessary" to achieve an agreement's efficiency-enhancing purpose. *See Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 224 (D.C. Cir. 1986) ("The ancillary restraint . . . it serves to make the main transaction more effective in accomplishing its purpose."); *Orson, Inc. v. Miramax Film Corp.*, 79 F.3d 1358, 1367-68 (3d Cir. 1996). Paragraph 3's description of the products covered was not only "reasonably necessary" but absolutely essential to enable the parties to settle. (ID 113).

V. THERE WAS NO CONSPIRACY TO MONOPOLIZE

Complaint Counsel concede, as they must, that their conspiracy count requires the heightened proof of "specific intent to monopolize." (CAB:77). *See, e.g., Belfiore v. New York Times Co.*, 826 F.2d 177, 183 (2d Cir. 1987) (specific intent requires that both parties share same intent to monopolize market); *In re Microsoft Corp. Antitrust Litig.*, 127 F. Supp. 2d 728, 731 (D. Md. 2001) (specific intent requires participation in illegal course of conduct for "specific, shared

purpose" of creating or maintaining monopoly). Complaint Counsel do not contend that there is any direct proof of such intent. Instead, they contend that there is indirect proof from which to "infer" specific intent. (CAB:77). But as established above, all of the nefarious "inferences" that Complaint Counsel seek to draw are unwarranted.

Furthermore, unrebutted evidence established that Upsher-Smith vigorously competed with Schering at all times relevant to the allegations (IDF 69; CX 740; USX 498) and promoted sales of its Klor-Con product line at the expense of K-Dur 20 (IDF 70-75). In addition, Upsher-Smith's legitimate business justifications — settling the litigation, guaranteeing accelerated entry of M20 and M10, liberating resources, expanding capacity, etc. — as a matter of law negate any inference of specific intent. *See Great Escape, Inc. v. Union City Body Co.*, 791 F.2d 532, 541 (7th Cir. 1986) (specific intent can be inferred only when conduct has no legitimate business justification other than to destroy or damage competition). Judge Chappell was right to find that, far from intending to further Schering's monopoly, "Upsher-Smith fought hard to bring its product to market and competed vigorously with Schering . . . ." (ID 119).

VI. JUDGE CHAPPELL DID NOT ABUSE HIS DISCRETION ON PROCEDURAL AND EVIDENTARY RULINGS

As their last gasp, Complaint Counsel argue that Judge Chappell abused his discretion with respect to certain evidentiary and procedural rulings. (CAB:78). As explained below, however, these rulings were perfectly proper.

A. Complaint Counsel Had A Full Opportunity To Seek Discovery From IPC Or To Call An IPC Witness At Trial

IPC is a manufacturer for Upsher-Smith. It is undisputed that longstanding contracts between the companies prohibit IPC from disclosing Upsher-Smith's confidential and proprietary information unless compelled to do so by law.

During the year-long Part II investigation, Commission staff interviewed IPC employees and obtained documents from IPC relating to the manufacturing of Upsher-Smith products. The information obtained from IPC was protected from public disclosure, and Upsher-Smith raised no objection.

In this Part III adjudication, IPC witnesses were identified on each side's witness lists. Upsher-Smith never raised any objection to Complaint Counsel obtaining discovery from IPC, as such discovery would have been obtained under the Protective Order Governing Discovery Materials. Nonetheless, Complaint Counsel never sought additional discovery from IPC during the six-month discovery period.

After discovery closed, IPC informed Upsher-Smith that Complaint Counsel had requested a private, off-the-record meeting with IPC officials to discuss Upsher-Smith proprietary information. Counsel for Upsher-Smith informed IPC's counsel that Upsher-Smith objected to such a private, off-the-record meeting, which was neither in conjunction with a Part II investigation nor a Part III deposition or trial. Upsher-Smith was concerned that its proprietary information would be discussed in a setting devoid of any safeguards and without a record. After Upsher-Smith raised these concerns, IPC voluntarily cancelled the meeting in light of its confidentiality obligations.

Judge Chappell was right to deny Complaint Counsel relief. Complaint Counsel had, through the passage of time, waived their right to take additional discovery from IPC. Complaint Counsel did not show "good cause" for circumventing the scheduling order. (Tr. 1961:5-17). IPC had no obligation to meet with Complaint Counsel on an informal basis. *See, e.g.*, *Pippinger v. Rubin*, 129 F.3d 519, 524 n.8 (10th Cir. 1997) (holding party "had no legal right to speak informally to any particular witness"); *Marens v. Carrabba's Italian Grill, Inc.*, 196

F.R.D. 35, 41 (D. Md. 2000) (holding "there is nothing in the discovery rules that gives a party the right to compel an informal interview"); *Byrnes v. United States*, 327 F.2d 825, 832-33 (9th Cir. 1964) (holding "any witness has the legal right to refuse to be interviewed"). And Upsher-Smith was well within its rights to request its manufacturing agent to honor contractual confidentiality obligations. *See In re ISP, Inc. Shareholders Litig.*, 789 A.2d 14, 73 n.180 (Del. Ch. 2001) (holding confidentiality agreement governing between business partners to be enforceable); *see also Coulter Corp. v. Leinert*, 869 F. Supp. 732, 735 (E.D. Mo. 1994) (recognizing cause of action for agent's breach of confidentiality). Complaint Counsel's reliance upon *Davis v. Dow Corning Corp.*, 530 N.W. 2d. 178, 181 (Mich. Ct. App. 1995), is off-base, because there the confidentiality in question, the physician-patient privilege, had been waived.

The IPC rulings are consistent with other courts which have harmonized one party's confidentiality rights with another party's right to evidence. For example, in *Uniroyal Goodrich Tire Co. v. Hudson*, 1996 WL 520789 (6th Cir. Sept. 12, 1996), the Sixth Circuit affirmed an injunction barring a former employee, covered by confidentiality agreement, from cooperating informally with the employer's litigation adversary, but permitting the former employee to testify in formal court proceedings, trial or deposition, "subject to appropriate notice and litigation safeguards." *Id*. at *5, 10-11. The Sixth Circuit found that this approach reconciled the public policy supporting "the fact-finding process" with the public policy supporting "the enforcement of valid contractual agreements." *Id*. at *10.

The IPC rulings do not compromise, or even implicate, Commission staff's investigatory powers. Commission staff spoke to IPC during the Part II investigation, and Upsher-Smith never objected. For this reason, reliance upon *EEOC v. Astra USA, Inc.*, 94 F.3d 738, 744 (1st Cir. 1996), is misplaced. Nor do Judge Chappell's rulings affect Complaint Counsel's rights in Part

III. Complaint Counsel could have taken the deposition of any IPC witness at any time during the discovery period. Furthermore, Complaint Counsel can claim no prejudice, as the ruling expressly left Complaint Counsel free to call any IPC witness at trial. (Tr. 1961:10-17).

On appeal, Complaint Counsel suggest for the first time that Upsher-Smith's counsel acted in violation of D.C. Bar Rule 3.4(f), but this suggestion is also meritless. First, Upsher-Smith's counsel communicated only with IPC counsel, not any witness. Second, Complaint Counsel misstate the rule in a way to obscure the fact that it expressly permits an attorney to request an "agent of a client," such as IPC here, to refrain from providing information to a litigation adversary. If there was any violation of professional ethics it was Complaint Counsel's attempt to induce IPC to breach its contractual obligations to Upsher-Smith. *See* D.C. Bar Rule 4.4 ("A lawyer shall not . . . use methods of obtaining evidence that violate the legal rights of [a third person].")

In short, Complaint Counsel has simply no basis to argue that Upsher-Smith "obtain[ed] silence" of any witness or that Judge Chappell "deprived the Commission (and any reviewing court) of relevant, reliable, and probative evidence." (CAB:82, 78). Complaint Counsel had every opportunity to obtain information from IPC during authorized Part II and Part III procedures and to call IPC witnesses at trial. But Complaint Counsel did not have the right to override Upsher-Smith's confidentiality rights in an extra-judicial setting.

B. Professor Bresnahan Was Unprepared To Provide Reliable Opinions On CX 43

Complaint Counsel next challenge Judge Chappell's ruling that Professor Bresnahan could not testify as to certain IMS substitution data. (CAB:82-85). This challenge, too, is meritless.

The "presiding officer at trial" enjoys the exercise of "broad discretion" regarding the admission of expert analysis. *Finley v. Marathon Oil*, 75 F.3d 1225, 1231 (7th Cir. 1996). Bresnahan, like all expert witnesses at trial, was required under the Scheduling Order and by Rule 3.31(b)(3) to provide prior and timely notice "of all opinions to be expressed and the basis and reasons therefor" in his report. *See also King v. Ford Motor Co.*, 209 F.3d 886, 900-01 (6th Cir. 2000) (excluding untimely disclosed expert testimony). Expert testimony not timely disclosed is routinely excluded. *See, e.g.*, *Geiserman v. MacDonald*, 893 F.2d 787, 790-92 (5th Cir. 1990) (excluding untimely disclosed expert testimony); *Lamarca v. United States*, 31 F. Supp.2d 110, 122 (E.D.N.Y. 1998) (excluding testimony exceeding bounds of expert's report). Bresnahan never provided any notice, in either his original report or his rebuttal report, that he would be offering opinions on physician or pharmacist substitution. (Bresnahan 8040:1-8044:20). Bresnahan never even identified CX 43, containing IMS substitution data, as a document he reviewed in connection with his work, and he never was deposed on it. *Id*. Judge Chappell plainly was on solid ground precluding Professor Bresnahan's testimony on this basis.

In addition, at trial it became painfully apparent that Bresnahan was utterly unprepared to provide reliable opinions on the IMS data in CX 43. After testifying that his understanding of the IMS data came from reading certain IMS manuals (Bresnahan 8048:12-21), Bresnahan was forced to concede that those manuals were incomplete, misassembled, and for the wrong periods. (Bresnahan 8050:3-8051:25). In addition, Bresnahan was also forced to concede that he did not know how the IMS data reflected the situation where a pharmacist called a physician and obtained authorization to substitute Klor-Con 10 for K-Dur 20. (Bresnahan 8049:1-8049:19). And this was exactly the point for which the evidence was to be introduced. *See* Commission

Rule 3.43; *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) (barring unreliable expert testimony).

Contrary to Complaint Counsel's suggestion, neither Respondents nor Judge Chappell ever expressed any objection to the general notion of an economist interpreting or opining on IMS data. Here, however, Bresnahan had not given proper notice of his intention to do so, and he was shown to be unprepared to provide reliable opinions. Judge Chappell was correct to bar Professor Bresnahan's testimony on this point.

C. Bazerman's Supplemental Report Was Two Months Late Without Good Cause

Complaint Counsel next argue that Judge Chappell abused his discretion in disallowing certain testimony by Professor Bazerman on risk aversion. But Complaint Counsel acknowledge that Profesor Bazerman's "supplemental" report was first disclosed two months after the deadline, and only one week before the trial began. (CAB:87). At trial, as their only explanation for their tardiness, Complaint Counsel stated: "[W]e didn't know that this witness had any knowledge in the area . . . ." (Tr. 7811:17-20). As the authorities cited in the previous subsection establish, given the degree of lateness, the lack of good cause and the potential to disrupt Respondents' trial preparations, Judge Chappell was well within his discretion in excluding Professor Bazerman's supplemental report and testimony. *See also Trilogy Communications, Inc. v. Times Fiber Communications, Inc.*, 107 F.3d 739, 744 (Fed. Cir. 1997) (excluding supplemental expert report as unjustifiably delayed where proponent of report could not show delay was result of opponent's actions).

Complaint Counsel cite Federal Rule of Civil Procedure 37(c) regarding the timely disclosure of expert reports (CAB:86 n.53). But courts applying Rule 37 have confirmed: "The sanction of exclusion is thus automatic and mandatory unless the party to be sanctioned can

show its violation of Rule 26(a) was either justified or harmless." *Finley*, 75 F.3d at 1230 (rejecting admission of untimely expert rebuttal evidence disclosed months late and only days before trial due to heavy burden it would impose on defendants to meet new analysis). Like the late-disclosing plaintiff in *Finley*, Complaint Counsel failed to make any such showing that the untimely disclosure would have been harmless; and they certainly have not shown the delay was justified — they admit it was of their own making. *See Trilogy Communications, Inc.*, 109 F.3d at 744.

D. William Groth Was Properly Excluded As An Improper Surprise Rebuttal Witness

Finally, Complaint Counsel argue that Judge Chappell abused his discretion in denying their extraordinary request, near the end of trial, to call a previously undisclosed witness, William Groth. Here, too, Judge Chappell ruled properly.

Complaint Counsel identified Groth literally months after all applicable deadlines. Groth was never listed on any of Complaint Counsel's witness lists. His name had never been mentioned in the case at all. He had never been deposed, and he had never produced documents. While Complaint Counsel argued that "unexpected" testimony of Upsher-Smith's Philip Dritsas justified the late identification of Mr. Groth, that argument was demonstrably unfounded.

Therapeutic substitution was a prominent issue from the very start of the case. In depositions, witnesses — including Mr. Dritsas — were asked and testified about it. At trial, Complaint Counsel's case-in-chief witnesses, especially Bresnahan, testified about it. (Bresnahan 432:8-433:9, 490:1-494:24). Bresnahan reviewed documents' that discussed substitution at the pharmacy level. (Bresnahan 454-455) (discussing SP 23 00048: "Develop and implement trade based programs … to discourage switching at the pharmacy level."). Bresnahan even testified about Mr. Dritsas's deposition on the subject. (Bresnahan 486:15-

487:15). When Dritsas testified on the subject, Complaint Counsel did not object. (Dritsas 4681:24-4683:21). Yet two weeks later, Complaint Counsel moved to add Mr. Groth, supposedly on the basis of Mr. Dritsas introducing some new subject.

In oral argument on Complaint Counsel's motion to add Mr. Groth, Complaint Counsel was forced to acknowledge that they had deposed Mr. Dritsas on therapeutic substition:

> **JUDGE CHAPPELL:** I just wanted to confirm that – do you deny that you questioned Mr. Dritsas about this issue of substitution during his deposition?
>
> **COMPLAINT COUNSEL:** I'm sorry, do we deny that we questioned him? No, we don't, Judge.

(Tr. 7491:15-20; *see also* Tr. 7411:6-7427:9). Thereafter, Judge Chappell denied Complaint Counsel's motion:

> I have reviewed the pleadings and the oral argument yesterday. I find that this issue was not a surprise, it was not unexpected. Therefore, the Government has not established good cause.

(Tr. 7491:21-25).

Judge Chappell showed great patience in allowing the parties to call witnesses. He set no limits at all on the number. In their case-in-chief, Complaint Counsel chose to call only three fact witnesses and three experts. Judge Chappell authorized Complaint Counsel to call nine rebuttal witnesses, many over the objection of Respondents. Mr. Groth was the only one he did not allow. This ruling, like the others Complaint Counsel have challenged on appeal, was correct and reasonable, and quintessentially within the discretion of a trial judge to administer proceedings fairly and efficiently. *See* Rule 3.43(b) (authorizing ALJ's "exercise of reasonable control over the mode and order of interrogating witnesses and presenting evidence").

CONCLUSION

Upsher-Smith is a manufacturer and marketer of generic pharmaceuticals. Its corporate mission is to compete with manufacturers of branded patented drugs by bringing reliable and affordable generic drugs to market. As such, Upsher-Smith recognizes and appreciates the public statements by the Commissioners advocating lower drug prices for consumers and extolling the benefits of generic competition.

Upsher-Smith has devoted substantial resources to defend this case before Judge Chappell and the Commission. It has done so not solely out of its shareholders' conviction that Upsher-Smith is innocent of any violation of federal law, but also because of their abiding belief that Upsher-Smith had done its best and made the most of a difficult situation. American consumers are currently enjoying the benefits and savings of Upsher-Smith's untiring efforts since 1995 to bring Klor Con M to market last September.

As Upsher-Smith's Ian Troup testified, it was he who initiated the telephone call to the managing executive of Schering (whose name and telephone number he had to look up). From that point forward, Mr. Troup persisted in negotiating the earliest possible date he could for entry of Upsher-Smith's generic product into the potassium market. And he was successful. Facing an entry date of 2005-2006, he negotiated all the way forward to entry in September 2001.

Ian Troup and Upsher-Smith did not conspire with Schering-Plough in any sense of the word. Rather, they fought hard all the way and concluded a uniquely procompetive settlement whereby consumers are accorded lower prices and expanded output for potassium products this very day.

Upsher-Smith requests that the Commission recognize the unique circumstances and features underlying this patent litigation settlement and affirm the decision of Judge Chappell dismissing the charges against Upsher-Smith.

Dated: September 30, 2002.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 3, 2002 I caused a paper original and twelve copies as well as an electronic copy of the public version of the Answering Brief of Upsher-Smith Laboratories, Inc. to be filed with the Secretary of the Commission:

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and one copy to be served by hand delivery upon:

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