UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

ORIGINAL

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

To: The Honorable D. Michael Chappell
Administrative Law Judge

COMPLAINT COUNSEL'S BRIEF IN SUPPORT OF PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

[PUBLIC VERSION]

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INTRODUCTION

"The antitrust laws are as much violated by the prevention of competition as by its destruction."[1] This case squarely raises the fundamental concern with the prevention of competition. It concerns an agreement to delay competition from a lower-cost generic alternative to a widely prescribed prescription drug taken by millions of older Americans who suffer from high blood pressure, heart disease, and other chronic conditions.

The Commission's complaint charges that Schering-Plough Corporation entered into unlawful agreements with two companies seeking to market a generic alternative to Schering's highly profitable potassium chloride supplement, K-Dur 20. In each instance, Schering settled its claim that the generic product infringed a patent covering K-Dur 20 through an agreement in which it agreed to pay the alleged infringer – $60 million in the case of Upsher-Smith Laboratories and $15 million to American Home Products Corporation – and the generic manufacturer abandoned defense of its product and promised to stay off the market for several years. The patent at issue in the litigations, which relates only to K-Dur 20's extended-release mechanism, could not guarantee that generic competition would not occur, and Schering did not expect that it would do so. Generic entry would cause Schering's $200 million annual K-Dur 20 sales to plummet, and even a month's delay in the introduction of a generic version would be highly profitable for Schering (but costly for consumers). By means of the agreements, Schering purchased a period of protection from generic competition.

Given the obviously anticompetitive nature of an agreement to pay a potential competitor to stay off the market, it is not surprising that respondents' primary defense in this case is to deny that this was what they agreed to. For its part, Schering does not dispute that both Upsher-Smith

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[1] *United States v. Griffith*, 334 U.S. 100, 107 (1948).

and AHP asked for multi-million dollar payments to stay off the market. The only dispute is whether Schering acceded to that request.

Schering says no, but its various attempts to explain away the written agreements are all unpersuasive, particularly because they are repeatedly undermined by contemporaneous documents that tell a different story. Schering relies on statements of its Associate General Counsel John Hoffman, who testified that he told Upsher-Smith and AHP that Schering would not pay them to stay off the market. But Schering's own documents show that: (1) far from being unwilling to enter into such an arrangement, Schering proposed (only a few months before its deal with Upsher-Smith) that AHP drop its generic product, and instead get paid to promote K-Dur 20; and (2) Schering's board of directors was told that the settlement with Upsher-Smith had to include payments to replace the income stream that Upsher projected it would forgo by agreeing to stay off the market for several years. Although Mr. Hoffman testified that he told Upsher-Smith that any payment under the settlement would have to "stand on its own two feet," Schering's documents show that the $60 million dollar payment to Upsher-Smith – purportedly for the Niacor-SR license – plainly did not.

While Schering offered its lawyer's statements in defense, it hid behind claims of attorney client privilege precluding exploration of whether his statements have any bearing on what actually transpired. Those statements plainly did not prevent the overtly anticompetitive proposal to AHP. And Schering's effort to justify the ultimate payment terms in its agreement with AHP by claiming that undue pressure from the trial judge and magistrate gave it no alternative – is implausible, in no small part because it rests on accusations of improper judicial behavior that are belied by the written record.

Although Schering admits that its would-be generic competitors asked for payments to stay off the market, and says it rebuffed those demands, it did not call as witnesses the key business executives who participated in the negotiations with Upsher-Smith. Despite the promise from Mr. Nields in his opening statement that he would call the negotiators, Mr. Driscoll, Mr. Kapur, and Mr. Wasserstein, to testify about those negotiations, he did not do so. We have the admissions of those absent witnesses from their investigational hearings and depositions, and their failure to be called to testify live at trial speaks volumes, because those sworn statements conflict with respondents' trial version of the story.

Because the challenged agreements amount to payments in return for a promise to stay off the market, they are on their face so plainly anticompetitive that they can be properly condemned as *per se* unlawful horizontal restraints of trade, absent some plausible argument that they were designed to promote a procompetitive goal. But the legality of the agreements does not depend on a conclusion that they qualify for *per se* treatment. The evidence establishes a violation, whether the agreements are judged under a *per se* standard or receive a closer examination under the rule of reason, looking to their likely harms and potential benefits to competition in the particular market context in which they arose.

The fact that these agreements were entered into in settlement of patent litigation does not in itself either provide a justification, or reduce their potential for substantial harm to competition. While patent settlements can promote competition, they can also be vehicles for anticompetitive conduct. This is evident from the Supreme Court's decisions in *United States v. Masonite Corp.*, 316 U.S. 265 (1942), *United States v. Singer Manufacturing Co.*, 374 U.S. 174 (1963), and other cases holding agreements settling patent disputes *per se* unlawful.

After denying the agreements involve payments to stay off the market, respondents suggest that the challenged agreements were in any event procompetitive because they allowed generic entry before expiration of Schering's patent. But is it really plausible that Schering would pay Upsher-Smith $60 million and AHP $15 million in order to promote *earlier* competition to its product? And any suggestion that the agreements were procompetitive because they served to guarantee an entry date before patent expiration is not a cognizable antitrust justification. The results of the competitive process are necessarily uncertain, but the antitrust laws rest on the fundamental premise that this process will produce the best results for consumers. The notion that competitors should get together and through mutually advantageous arrangements set a schedule in order to guarantee generic entry is no more legitimate than an argument that consumers would be better off with guaranteed prices fixed by competing sellers.

Respondents' other purported justification – that payments may be necessary to reach procompetitive settlements – is merely post-hoc rationalization. While their economic experts theorize about possible circumstances in which a payment for a future entry date might not result in delayed entry, each theory actually is a road-map to anticompetitive conduct, showing that the parties will always be better off by paying additional compensation for further delayed entry. In any event, no evidence suggests that respondents' theories could explain the payments challenged in this case – their economic experts never attempt to apply their theoretical models to the facts of this case – or even suggest that the type of payment at issue here has ever been used to reach a procompetitive settlement.

Anticompetitive agreements among competitors are unlawful even when they do not threaten to create or maintain a monopoly. In this case, however, the agreements also amount to

acts of monopolization and unlawful conspiracies to monopolize. Prior to generic entry, Schering possessed what the law defines as monopoly power – that is, "power to control prices or to exclude competition" – and the agreements preserved that power. Respondents spent a great deal of time at trial establishing what we readily acknowledged at the outset: that K-Dur 20 is one of several potassium supplements on the market. But the stubborn facts concerning the unique impact of generic K-Dur 20 on Schering's sales cannot be denied or explained away.

Respondents' violations require an order to prevent further illegal conduct. The stakes for consumers here are enormous. An order is necessary to prevent the respondents from engaging in similar anticompetitive agreements in the future. A proposed order is attached.

I. STATEMENT OF FACTS

The Commission's complaint in this case challenges two separate agreements, one between Schering and Upsher, and another between Schering and AHP. The agreements settled patent infringement suits brought by Schering against these companies after they sought approval to market generic versions of one of Schering's products, K-Dur 20. The agreements share many common features:

- substantial, up-front, non-contingent cash payments from Schering, the patent holder, to the alleged infringers ($60 million to Upsher, and $15 million to AHP);
- agreement by the potential generic competitor to refrain from launching its product for several years, instead of seeking an earlier entry date through a victory in the patent litigation;
- other restraints to prevent generic entry, including a promise not to enter with any 20 milliequivalent ("mEq") potassium supplement, regardless of whether it infringed Schering's patent; and
- licenses to Schering for other products that are unrelated to the subject of the patent litigation.

A. Schering's K-Dur 20

Schering sells a widely-prescribed potassium chloride supplement known as K-Dur 20, which is used by millions of Americans, particularly older people suffering from high blood pressure. Potassium chloride supplements are used to treat potassium deficiency (known as "hypokalemia"), a condition that often arises among individuals who take the diuretic medications that are used to treat high blood pressure or congestive heart disease. Because these are chronic conditions, K-Dur 20 is generally a long-term therapy. CPF 940.

K-Dur 20 is the most frequently prescribed potassium chloride supplement in the United States. Until Upsher's entry in September 2001 with its generic product, Klor Con M20,

Schering's K-Dur 20 was the only potassium chloride product in a 20 millicquivalent extended release tablet or capsule. K-Dur 20 has certain unique features that give it an advantage over the various other potassium supplements available to consumers. Throughout the early and mid-1990s, Schering raised prices and increased sales and profits from K-Dur 20, despite the existence of lower-priced potassium chloride products. Both the price increases and increasing sales volume enhanced the profitability of the product. CPF 950. By 2000, Schering's sales of K-Dur 20 had reached almost $260 million, and of that over 80% was gross profit.[2]

B. K-Dur 20's Limited Patent Protection

K-Dur 20 was an attractive target for generic entry not only because of the large profits that Schering enjoyed, but also because Schering's patent protection (which could prevent entry) was relatively narrow. K-Dur's active ingredient, potassium chloride, is a substance in common use and is unpatentable. The patent covering K-Dur 20 (known as the '743 patent) relates only to the extended-release mechanism of the product. It concerns the coating used on the potassium chloride crystals that make up the K-Dur 20 tablet, and in particular the type and viscosity of the material used for the coating. A generic manufacturer would therefore not infringe the '743 patent as long as it did not use the type of coating covered by the patent. CPF 67-73.

Schering expected that generic entry would take place before the patent's 2006 expiration date. CPF 75-79, 81-82. For example, a 1995 memorandum from the product manager for K-Dur to company executives advised that "direct generic competition is expected" and warned that

[2] CPF 976 (total K-Dur sales and product margins), 987 (K-Dur 20 percentage of K-Dur).

it might come as early as 1997.[3] In light of that anticipated competition, the objectives would be to "maximize length of time to introduction" and "minimize market penetration." CX 13 at SP 003048. A late 1995 memorandum, authored by Schering executive Martin Driscoll, discussed the timing needed to launch an in-house generic product concurrent to entry by a competitive generic version of K-Dur 20. CX 15 at SP 003885. By 1996, after two companies had filed applications seeking FDA approval to market a generic version of K-Dur 20, internal estimates predicted that "generic entry is not likely until 1998." CX 17 at SP 003946; CPF 76.

C. The Threat of Generic Entry

The congressional scheme for approval of generic drugs – commonly referred to as "the Hatch-Waxman Amendments" – encourages companies to undertake challenges to patent validity or to design around valid patents. A generic applicant files an Abbreviated New Drug Application ("ANDA") to establish that its product is bio-equivalent to its branded counterpart. The first company that seeks FDA approval for a generic alternative to a branded drug still covered by a patent, and certifies to the FDA that the patent in question is invalid or not infringed (known as the "Paragraph IV certification"), is eligible for a 180-day period of market exclusivity. No other generic manufacturer may obtain FDA approval to market its product until the first filer's 180-day exclusivity period has expired. CPF 902-903. In 1995, both Upsher and AHP sought FDA approval to market a generic version of K-Dur 20.

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[3] CX 13, Memorandum from Andrea J. Pickett, Product Manager, K-Dur, Re: K-Dur Long Term Strategy (March 8, 1995), at SP 003044.

1. Upsher-Smith

Upsher filed an ANDA seeking FDA approval for a generic version of K-Dur 20 in August 1995. It was the first to file an ANDA certifying that its product did not infringe Schering's '743 patent. That certification meant Upsher was eligible for the 180-day exclusivity period provided under Hatch-Waxman. Schering sued Upsher, claiming the product infringed the '743 patent. Upsher consistently denied any infringement, and maintained that it had successfully designed around the '743 patent. CPF 90-95.

As the litigation progressed, Upsher became a more imminent threat to Schering's K-Dur 20 profits. Upsher received tentative FDA approval (CPF 22) for its product in March 1997, and was making plans to launch its product in late 1997 or early 1998. CPF 118-124.

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With a June 1997 trial date approaching, in May 1997 the parties began to negotiate a settlement. On the eve of trial, the parties reached a settlement agreement. Schering agreed to pay Upsher $60 million, in three unconditional payments over a two-year period. Upsher in turn

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[4] . . . . . ; CPF 122.

agreed not to launch any generic competition to K-Dur 20 for over four years, until September 2001. In addition, the parties agreed to a bundle of licenses from Upsher to Schering, which granted marketing rights outside the United States, Canada, and Mexico for Niacor-SR (a sustained-release niacin product designed to treat elevated cholesterol) and certain other products. CX 348 at USL 03186-93, Schering/Upsher Agreement, 6/17/97.

2. AHP

AHP's generic unit, ESI-Lederle, Inc. (hereinafter "AHP"), filed an ANDA seeking FDA approval for a generic version of K-Dur 20 in December 1995. AHP certified to the FDA that its product did not infringe Schering's '743 patent, and stated that its product did not use the coating mixture claimed in Schering's patent. Shortly thereafter, Schering brought a patent infringement suit against AHP. CPF 814-815, 822.

As in the case of Upsher, AHP's generic product presented a threat to Schering's K-Dur 20 profits. There was greater uncertainty, however, in AHP's case, particularly because of Schering's agreement with Upsher. Upsher, the first ANDA filer on K-Dur 20, was eligible for the 180-day exclusivity period under Hatch-Waxman. Until that right expired, entry by other generic competitors would be blocked. Court decisions at that time, however, had made it unclear whether Upsher had lost its exclusivity rights when it settled with Schering. CPF 911-915. The source of this uncertainty was the continued viability of a 1994 regulation, which required the first generic filer to "successful[ly] defend" the patent infringement suit to qualify for the 180-day exclusivity period. Under the successful defense regulation, by settling the patent litigation Upsher would have lost any claim to a 180-day exclusivity period. Before Schering's

agreement with Upsher, however, a federal court had found this regulation to be invalid. Thus, in June 1997, the "successful defense" regulation appeared to be on the way out. CPF 906-910.

If Upsher retained the exclusivity rights, then its agreement not to launch its product could prevent AHP from entering the market until March 2002 (180 days after the agreed-to entry date for Upsher in September 2001). Shortly after Schering entered into its agreement with Upsher, however, a different federal district court held the FDA's successful defense regulation was lawful and valid. In addition, the FDA announced that a decision of patent invalidity or non-infringement in a lawsuit involving any ANDA filer – not just the first one – would trigger the first filer's 180-day exclusivity period. Thus, the likelihood that Schering's agreement with Upsher would block AHP's ability to enter before 2002 became more uncertain. Only in April 1998 did it become clear that Upsher retained its exclusivity rights.[5]

The parties settled the case in January 1998, with an agreement similar in several respects to the one Schering had entered into with Upsher six months earlier. The agreement, which was finalized in June 1998, provided for Schering to pay AHP $15 million - $5 million up-front and the remaining $10 million conditioned on AHP's obtaining tentative FDA approval by June 1999.[6] AHP ultimately received FDA approval in May 1999, and Schering paid it the $10 million. The agreement, like the one with Upsher, also set an entry date several years in the future: AHP agreed not to launch its generic product until 2004. The parties also agreed to a

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[5] *See, e.g.*, Tr. 10:2194, 2269-71 (Joel Hoffman); Tr. 28:7005-08, 7024 (Safir) (up to a 50% chance that an AHP decision would trigger Upsher's exclusivity); *see also* CPF 842-843, 916-922.

[6] CX 484, Settlement Agreement, re: Key Pharmaceuticals v. ESI-Lederle, Inc. (6/19/98), at AHP 0500060-61.

variety of other restrictions barring AHP from supporting or promoting any generic competition to K-Dur 20. Finally, Schering purchased a license to two generic products held by AHP, and Schering agreed to pay an additional $15 million to AHP for those licenses.

II. THE EVIDENCE SHOWS SCHERING PAID UPSHER AND AHP TO STAY OFF THE MARKET

There is no dispute that, under their agreements, Schering paid Upsher $60 million and AHP $15 million, and that these potential generic entrants agreed not to launch their products for several years. There is also no dispute that each party abided by its agreement, and that generic competition to K-Dur 20 did not occur until September 2001, more than four years after Upsher abandoned its patent infringement case. What is disputed is whether Schering's substantial payments to its only two potential competitors at the time were consideration for their promises to stay off the market with their low-cost generic alternatives to K-Dur 20.

The agreements themselves, as well as the substantial evidence adduced at trial, resolve this dispute. It proves that Schering's payments to Upsher and AHP were to prevent generic entry for several years and thereby protect Schering's K-Dur 20 revenue stream. It shows that respondents not only had ample incentives to enter into agreements to delay generic entry, but also that they acted on those incentives. This evidence includes the written agreements themselves, contemporaneous business documents describing the agreements, the parties' own testimony, and the expert opinions of a preeminent economist and an accomplished pharmaceutical executive and consultant. All this evidence points in one direction: Schering paid its competitors millions of dollars to drop their patent disputes, set entry dates several years down the road, and thereby protect Schering's K-Dur 20 revenue stream.

A. Schering Paid Upsher to Secure Its Agreement Not to Enter Until 2001

1. The terms of the agreement show payment for the entry date

The most direct evidence of the purpose of the $60 million in payments to Upsher is the parties' written agreement itself. This agreement, on its face, establishes that Schering's payments were, at least in part, "consideration" for Upsher's agreement not to launch any generic version of K-Dur 20 for over four years, until September 2001.

- ***Schering's $60 million payments are directly linked to Upsher's agreement to the entry date***

Paragraph 11 of the Detailed Agreement Terms explicitly states that Schering's payments including the so-called "up-front royalty" payments of $60 million over two years – are "[i]n consideration for the licenses, rights and obligations described in paragraphs 1 through 10 above."[7] Paragraph 3 sets forth Upsher's obligation not to go to market before September 1, 2001. Thus, as Schering's in-house counsel could not dispute on the stand, the very terms of the agreement show that the payment was at least in part consideration for Upsher's promise to stay off the market until 2001.[8]

Despite Schering's concession, Upsher's President, Ian Troup sticks to his story that the cited language of Paragraph 11 must be some sort of "typo" because, according to him, the payments were not meant to be in consideration for Upsher's agreement to stay off the market. Tr. 23:5555-56 (Troup). The terms of the contract, however, are "clear and unambiguous."

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[7] CX 348, Settlement and License Agreement (6/17/97) at USL 3188.

[8] Tr. 15:3565-66 (John Hoffman) ("Q: Okay, so on the face of this agreement, it's explicit and clear, is it not, that the money to be paid was paid at least in part for the settlement of the lawsuit? A: You could interpret it that way. Q: Sir, isn't that explicit? A: I don't want to quibble with you.").

Accordingly, under New Jersey contract law, which governs the interpretation of the Schering/Upsher agreement,[9] "there is no room for [Mr. Troup's] interpretation;" it must be ignored as the plain language of the contract controls.[10]

- ***Upsher's obligation to abide by the entry date is directly linked to Schering's obligation to make the $60 million payments***

Paragraph 3 of the agreement provides that, should a court invalidate those portions of the agreement obligating Schering to pay Upsher the $60 million, then Upsher suddenly would be free to market its generic K-Dur 20 product prior to September 2001. In simple terms, this means that if Schering is not required to make the entire $60 million in payments, Upsher is not required to stay off the market for the entire agreed upon term until September 2001. This provision shows that Schering's commitment to pay the $60 million is not part of some separate and distinct licensing agreement, as respondents claim, but is rather inseparable from Upsher's commitment to stay off the market – until September 2001.

- ***In contrast, Schering's $60 million payments are not linked to the development or approval of the licensed products***

Schering purportedly paid $60 million up-front for the rights to Niacor-SR and several other Upsher products. Yet, under the Schering/Upsher agreement, these substantial payments are not linked in any way to the development, regulatory approval, or marketability of these

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[9] CX 348 at USL 03184.

[10] *County of Morris v. Fauver*, 707 A.2d 958, 968-69 (N.J. 1998) (holding that "where the terms of the contract are clear . . . the court must enforce it as written," even where both parties have misconstrued it); *City of Orange Township v. Empire Mortgage Serv., Inc.*, 775 A.2d 174, 179 (N.J. Super. Ct. App. Div. 2001) (applying "well-settled principle[] of contractual interpretation" that "where the terms of a contract are clear and unambiguous there is no room for interpretation or construction and the courts must enforce those terms as written").

products.[11] As Schering concedes, the $60 million in up-front payments were "guaranteed" (CPF 251); its obligation to make these payments was not contingent on "anything"[12] – not on regulatory approval; not on Upsher's best efforts to further develop the products; not even on any efforts to continue development activities.[13] In fact, Schering paid $32 million in installments on the $60 million well after Upsher had abandoned all efforts to seek regulatory approval for Niacor-SR as a new drug.[14]

- ***The force majeure clause is consistent with payment for the entry date***

The agreement's "*force majeure*" clause (Paragraph 20) also undermines respondents' claims that the $60 million payment was not for the agreement to the 2001 entry date. This clause – which provides that a failure to perform obligations under the contract shall not constitute a breach where the failure to perform is due to a cause outside the control of the non-performing party – expressly exempts "the obligation to make payments when properly due."

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[11] Tr. 15:3569 (John Hoffman). Although Schering obtained in its agreement licenses to five Upsher products, Schering officials realized that those other products were of minimal significance. CX 338, Presentation to Schering Board of Directors at SP 12 00271 ("other products under license . . . are less significant than Niacor-SR"); CX 1510 at 40 (Kapur IH) ($60 million payment was basically for Niacor-SR, and the other "ancillary" products were just "thrown in"); Tr. 23:5523-24 (Troup) (testifying that Niacor was the "most valuable asset" in the agreement).

[12] CX 1529 at 140-41 (Troup IH).

[13] Schering-Plough's Response to Complaint Counsel's Revised Second Request for Admissions, No. 70; Tr. 15:3570-72 (John Hoffman); Tr. 19:4391, 4393-94 (Lauda); CPF 247-257.

[14] Upsher put on hold its efforts to submit a new drug application for Niacor-SR in January 1998. Tr. 17:4051 (Halvorsen); CX 962 at USL 13253 (as of 1/15/98, "Project has been put on hold"). Under the agreement, Schering made a $20 million payment to Upsher in June 1998 and another $12 million payment one year later. Schering-Plough's Response to Complaint Counsel's Revised Second Request for Admissions, Nos. 74-75.

Thus, Schering's obligation to make the $60 million in payments to Upsher would continue even if some act of God or other *force majeure* made the product licenses it received from Upsher totally worthless, so long as Upsher continued to withhold its generic K-Dur 20 from the market. CX 348 at USL 03193.

2. Schering had a powerful incentive to delay generic entry by paying Upsher a share of its profits

Although Schering owns a patent covering K-Dur 20 that did not expire until 2006, Schering expected generic entry well before that time.[15] This is because the patent covering K-Dur 20 (known as the '743 patent) relates only to the extended-release mechanism of the product. As a result, Schering was vulnerable to a company successfully designing around the patent, and entering with a non-infringing generic equivalent.

And Schering had a great deal to lose from such entry. For it is well established in the economic literature, and well understood in the pharmaceutical industry, that when generic entry does occur, the branded drug company suffers a rapid and steep decline in sales and profits.[16] Empirical research has shown that within the first full year after launch of a generic product, branded drugs lose an average of 44 percent market share to the generic product.[17] Schering was

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[15] *See, e.g.*, CX 13 at SP 003044 (1995 internal Schering memorandum noting that generic competition to K-Dur 20 may come within two years); CX 124 at SP 23 00316a (assuming generic K-Dur 20 launch in 1997); CX 128 at SP 23 00325a-26a (Key Five Year Sales Forecast assuming generic K-Dur 20 entry in July 1997); CPF 74-82.

[16] Tr. 1:130 (Goldberg) (generics have approximately 75-80% market share of K-Dur 20 market); Tr. 2:210-11 (Teagarden) (within 90 days of generic entry 70-90% conversion from brand to generic, contributing to 30-60% decrease in cost of drug).

[17] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* at xii (July 1998).

acutely aware of the threat that a generic version of K-Dur 20 would pose. • • • • • • • • • • •
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• •[18] When generic competition finally began in September 2001, the adverse impact on Schering's sales was even more dramatic than projected. By December 2001, after only three months of generic competition, over 70% of new prescriptions for K-Dur 20 were filled with the generic product.[19]

The prospect of such substantial losses gave Schering a powerful incentive to pay for protection against such competition. The evidence showing that other potassium chloride products did not constrain Schering's ability to price its product well above what a generic would charge, as well as the evidence showing the unique ability of generic entry to take sales away from Schering, support the conclusion that Schering had monopoly power in K-Dur 20. CPF 943-947. Where a firm, like Schering, possesses monopoly power, entry will lower prices and reduce the incumbent's profits. Although some of these lost profits are captured by the entrant, some will flow to the consumer in the form of lower prices. This means that the incumbent earns more without competition than the combined profits of the two competitors after entry. Tr. 3:426 (Bresnahan).

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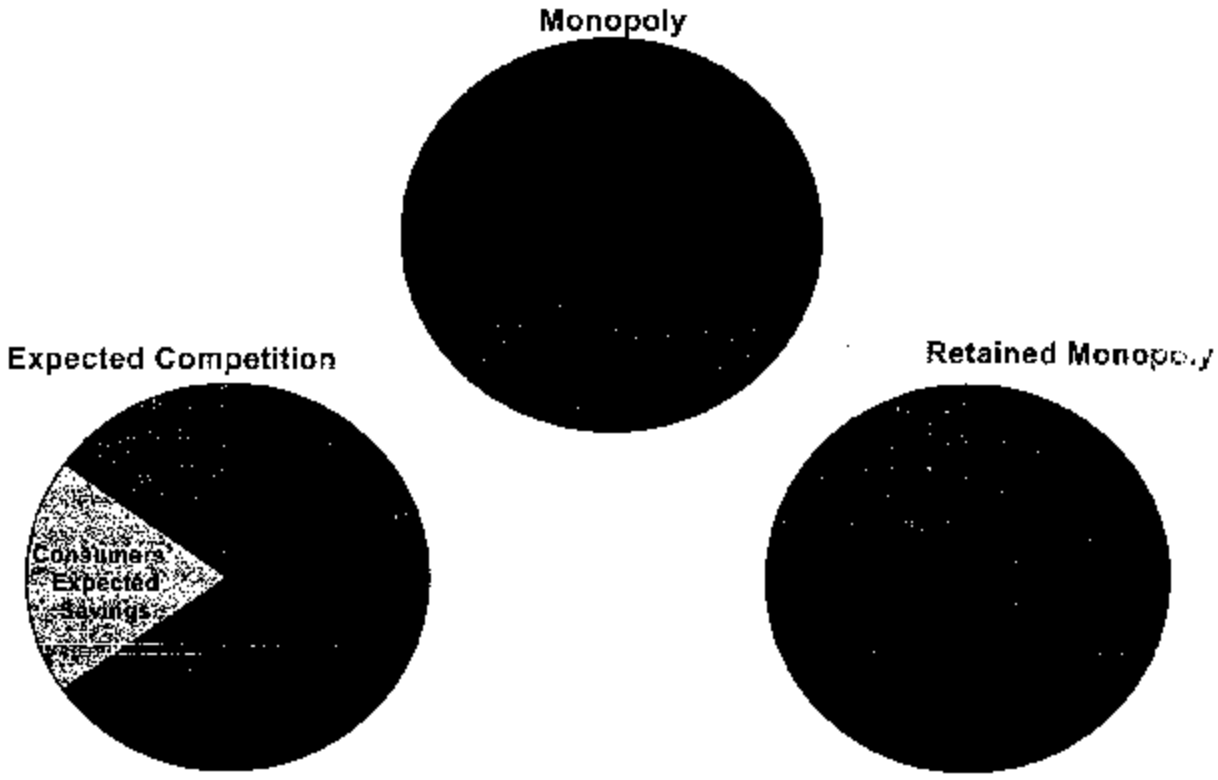
[19] CX 1480 at SP 089837.

As a result, the incumbent, Schering in this case, can always afford to use a portion of its profits to compensate the would-be generics for staying out of the market, and still benefit from extending its monopoly, as illustrated below:

Incentives to Pay to Delay Expected Competition



As Professor Bresnahan cautioned, however, what is good for Schering – the incumbent monopolist and its generic competitors is not so good for consumers: By keeping out competition, and thereby preserving higher monopoly prices, Schering "take[s] money from the consumers" and then gives a "chunk" of that money "to the entrant so that it's in their interest not to come in." Tr. 3:426-29 (Bresnahan). The result: consumers lose the opportunity to reap the savings generic entry offers.

3. The evidence shows that Schering and Upsher acted on their incentives to delay generic entry

Respondents acted on their incentives to delay generic entry. This is shown through respondents' own testimony about the negotiations that resulted in the Schering/Upsher agreement, as well as their contemporaneous business records.

- ***Upsher negotiated for compensation to stay out of the market***

From the first meeting to discuss settlement of the Schering/Upsher patent litigation, Upsher's sole negotiator (Ian Troup) made it very clear that he expected Schering to compensate his company to replace the forgone revenues for delaying his generic K-Dur 20 entry. As told by the Schering officials participating in these negotiations (only one of whom appeared live at trial), Mr. Troup was "very insistent" throughout the negotiations that Schering provide Upsher with "an up-front payment and cash" as part of any settlement. CX 1531 at 88- 89 (Wasserstein IH).

In the words of Martin Driscoll, Schering's former Vice President of Marketing, Mr. Troup "wanted a payment to come off the market, for them to stay off the market." CX 1494 at 71. He discussed "rather extensively" that Schering should make a "payment in the neighborhood of $60 to 70 million" to end the litigation, and that this payment should be based on a percentage of the K-Dur 20 sales Schering would retain if Upsher agreed to withhold its generic product from the market. CX 1494 at 65-67 (Driscoll IH). Mr. Troup was "pretty forceful . . . very forceful as a matter of fact" in this demand, and would not "move off their position." CX 1494 at 65-66, 71 (Driscoll IH).

Raman Kapur had a similar recollection: Upsher was "looking for a revenue stream to replace" his expected income from generic K-Dur 20, and "if his [generic K-Dur] entry was delayed in terms of the revenue stream that he hoped to make [that] up."[20] And Schering's Associate General Counsel testified that Mr. Troup invited Schering to "pay Upsher-Smith to stay off the market."[21]

- ***Schering understood that it needed to compensate Upsher to stay off the market and that the payment amount needed to reflect Upsher's forgone generic K-Dur 20 revenues***

Schering's contemporaneous business documents provide the best evidence of what Schering believed to be the purpose of its $60 million payments to Upsher. Although Schering now tries to explain away what appears on the face of its own documents,[22] this evidence plainly shows that Schering had no doubt that the money would be used to provide Upsher with a "guaranteed income stream" to compensate Upsher for staying out of the market.

Indeed, this is precisely what Schering management told its Board of Directors while seeking approval for the proposed agreement. As stated in the June 1997 presentation to the Schering Board of Directors, Upsher was seeking an "income stream to replace the income that Upsher-Smith had anticipated earning if it were able successfully to defend against Key's

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[20] CX 1510 at 104 (Kapur IH); CX 1511 at 19-20 (Kapur dep).

[21] CX 1509 at 33 (John Hoffman dep); *see also* CPF 200-202.

[22] *See, e.g., United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1948) (where trial testimony is contradicted by contemporaneous documentary evidence, the testimony should be given little weight); *Adolph Coors Co.*, 83 F.T.C. 32, 326 (1973) ("It is well established, however, that little weight can be given to testimony which is in conflict with contemporaneous documents, particularly when the crucial issue involves mixed questions of law and fact.").

infringement claims," and, according to Upsher, this "guaranteed income stream" was "a prerequisite" for any agreement:

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

CX 338, Board of Director's Presentation (June 24, 1997, at SP 12 00268-270).

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• Schering licensed a bundle of products from Upsher. It arranged to pay Upsher $60 million over a two-year period. The discounted value of these $60 million payments • And in exchange for Schering's payment to Upsher of the revenues it expected to obtain from its generic K-Dur 20 sales, Upsher agreed to forgo competition with Schering until September 2001.

4. The $60 million payment was not for the Niacor-SR license

Schering attempts to defend the $60 million payment as part of the compensation that it paid for a license to a different product, Niacor-SR. Although the Niacor-SR license had other, conventional royalty terms, Schering has claimed that the enormous up-front non-contingent payment simply was further compensation for Niacor-SR. The evidence refutes that argument.

- ***Neither Upsher nor Schering had any sound basis upon which to value the Niacor-SR license when they agreed to the $60 million payment***

The parties' negotiations over the payment amount makes clear that the $60 million payment is not for the Niacor-SR license, as respondents claim. At the same time Schering and Upsher supposedly were in the midst of negotiating an up-front payment virtually unprecedented in size in the pharmaceutical industry (and the largest in Schering's history), neither party had any basis for valuing Niacor-SR, the principal product at stake.

Mr. Troup readily concedes he made no effort to quantify the value of a Niacor-SR license outside of the United States at the time of the settlement agreement. He did not confer with the European consultant Upsher hired specifically to identify a licensing partner for Niacor-SR. Nor did he confer with the Upsher official who recently had returned from Europe after meeting with several potential licensing partners. Tr. 23:5524-25, 5541, 5544-47 (Troup).

Mr. Troup certainly could not appraise the value of Niacor-SR based on what other companies were willing to pay. Although Upsher had spent the previous five months contacting "virtually everybody who is a pharmaceutical manufacturer or distributor outside of the United States," most showed no interest, and none offered any non-contingent payment whatsoever.[23] And Upsher's modest internal estimates of Niacor-SR's potential – predicting U.S. annual sales to be as little as $3.3 million and no more than $20 million[24] – provide no basis to support such an extraordinary $60 million up-front licensing fee.[25]

In the end, Mr. Troup justifies his substantial payment demand only by pointing to his own mental calculation, based on another company's public sales forecasts for a different product to be sold in a different part of the world. Tr. 23:5524-26 (Troup). How can this flimsy and

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[23] Tr. 28:6931 (Kerr). One of the companies which initially expressed some interest – Searle – ultimately rejected the licensing opportunity because, according to the head of the licensing project, Niacor-SR "was not going to be a successful drug." Tr. 33:7885-86 (Egan); *see* CPF 778-808.

[24] CX 234 at USL12785 (estimating Niacor-SR annual sales at $3.3 million); CX 322 at USL 05287 (long term planning document forecasting $20 million in Niacor-SR annual sales); CX 778 at USL 15531 (estimating Niacor-SR annual sales at $7 - 8 million); CX 1094 at USL 11935 (estimating Niacor-SR annual sales at $11.5 million); *see also* Tr. 23:5533-41 (Troup).

[25] U.S. sales of pharmaceuticals are generally assumed to be "roughly half of the worldwide sales." Tr. 7:1333-34 (Levy).

untestable explanation be credited, particularly where Troup's $60 million demand matches almost precisely Upsher's estimated lost generic K-Dur 20 revenues?

Schering's unorthodox approach to the settlement discussions also reveals the true purpose of the up-front payments. Schering did not negotiate the $60 million payoff from having previously assessed the value of the Niacor-SR licensing opportunity, as would be expected if the payment was actually in consideration for the licensed product. Instead, Schering arrived first at the $60 million price tag.[26] And only then did it purportedly analyze whether the product was actually worth the amount negotiated.

Mr. Lauda, one of the Schering executives involved in the Niacor-SR evaluation, described his assignment this way: Ray Kapur "informed me that they had an opportunity to license several projects – several products, from Upsher . . . and could I perform an assessment of that against a background that the value would probably -- the payment would probably be about $60 million." CX 1515 at 86 (Lauda IH).[27] In other words, Schering had already decided to pay Upsher $60 million, and now it needed something to justify that decision. While Schering had not valued Niacor-SR prior to its negotiations with Upsher, •

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[26] CPF 242; *see* CX 1515 at 102 (Lauda IH). Raman Kapur, the principal Schering representative involved in the negotiations, was in charge of Schering's generic operation. In the words of Schering's counsel: "He was not qualified to evaluate Niacor." Tr. 1:55-56 (Schering's opening statement).

[27] *See also* CX 1516 at 40 (Lauda dep) (Kapur "mentioned to me that it was an arrangement that they were looking to have a value of about $60 [million], was it worth $60 [million].").

- ***The $60 million non-contingent payment is grossly excessive in light of Schering's licensing practices and standard practices in the industry***

The terms of the license agreement are unremarkable in all respects save one: the huge non-contingent payment. This $60 million cash payment greatly exceeded fees paid in other transactions by Schering, including those with far greater value than the products received under the Schering/Upsher agreement.[28] Indeed, it remains the largest payment of its kind in Schering's history.

This unprecedented payment is even more striking because it was for a drug (Niacor-SR) which, in the context of billion dollar pharmaceutical licensing opportunities, had "very low value."[29] According to Schering's own internal estimates, Niacor-SR was expected to generate sales of between $45-149 million per year.[30] As Mr. Lauda testified, "100 million is not a hugely successful product in the United States." Tr. 19:4434 (Lauda).

The agreement also lacks the ordinary protections that would be expected in such an agreement. •

[28] Tr. 7:1329-30 (Levy); CPF 259, 314-327.

[29] Tr. 7:1330 (Levy); *see also* Tr. 7:1331-33 (Levy) (explaining that even under the most optimistic projections, Niacor-SR's sales would rank only around 300th among pharmaceutical products).

[30] CX 1044 at SP 1600047 (Mr. Audibert's "commercial evaluation" of Niacor-SR).

• • • • • • .[31] But in this agreement, Upsher, the licensor, received the $60 million payments free and clear, without any obligation to do anything further.[32]

- ***Schering's five-day evaluation of Niacor-SR fell far short of industry licensing standards and Schering's own due diligence practices***

Far from being extraordinarily diligent – as might have been expected in a deal where the amount of up-front cash committed was unprecedented – Schering's due-diligence in the evaluation of Niacor-SR was noticeably superficial. It failed to follow the procedures ordinarily used by Schering and those generally adhered to in the pharmaceutical industry.[33]

A single employee, James Audibert, carried out the purported due-diligence in less than five days.[34] He did so without input from the groups ordinarily involved in licensing decisions, that is, Schering's research and development group, patent counsel, regulatory group, manufacturing group, finance group, or any of the normal due diligence groups with responsibility for marketing and selling the product. CX 1484 at 89-91 (Audibert dep).

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[31] • ; Tr. 26:6316-17 (Kerr) ("[M]ore than in most other industries, [in the pharmaceutical industry] there is a substantial risk that any particular product in the pipeline at any time won't get into the market."); Tr. 19:4389-90 (Lauda) (confirming that some drugs which reach the last stage of clinical development never receive FDA approval).

[32] Tr. 7:1322, 7:1324-25 (Levy); *see also* CPF 291, 304, 328-333; Tr. 19:4391 (Lauda) (confirming that payments were noncontingent).

[33] *See* Tr. 7:1341 (Levy) ("It just fell dramatically short of any evaluation process that I've encountered for a pharmaceutical of this type.").

[34] *See, e.g.*, Tr. 18:4161-66 (Audibert); CX 1483 at 31-32 (Audibert IH); CPF 375, 419-442, 456-484.

As the chart below demonstrates, Schering's Niacor-SR due diligence efforts were far more cursory than in comparable Schering licensing deals, and conducted in a fraction of the time, even though the agreed-to cash payment was the largest of its kind.

Schering's Superficial Due Diligence[35]

	Upsher-Smith's "Niacor-SR"	Atherogenics "AGI-1067"	British Biotech's "Marimastat"	Zonagen's "Vasomax"	COR Therapeutics "Integrelin"	ICN's "Ribavarin" (Infliximab)
Research & Development Review		•	•	•	•	•
Regulatory Review		•	•	•	•	•
Intellectual Property Review		•	•	•	•	•
Financial Review	√	•	•	•	•	•
Commercial Assessment	√	•	•	•	•	•
Manufacturing Assessment		•	•	•	•	•
Time Spent on Due Diligence	no more than 5 days	• • • •	• • • •	• • • •	• • • •	• • • •
Up Front Payments	$60 million	• • • •	• • • •	• • • •	• • • •	• • • •

That Schering conducted a superficial review of Niacor-SR is not seriously disputed. Schering's Executive Vice President of Global Marketing (Thomas Lauda) acknowledges that Schering "did a lower amount of due diligence for the Niacor project" than for the many other licensing deals with which he has been involved. Mr. Lauda's only explanation for Schering's meager due diligence efforts is •

[35] *See* CPF 485-486.

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• • • • • • • • • • • The evidence directly refutes these claims.

First, Niacor-SR was anything but • • • • • • • • • • • • :

- Although *niacin* was well-known and, as of the Schering/Upsher agreement, had been marketed for years, no company had successfully developed, and received approval for, a *sustained-release version of niacin*.[36]

- Sustained-release forms of niacin had known liver toxicity problems problems with which Schering was well aware. Just two months prior to agreeing to pay $60 million in exchange for one sustained-release niacin product (Niacor-SR), Schering had commissioned a survey of ten medical experts to evaluate the clinical aspects of a different sustained-release niacin drug (Niaspan). The results of that survey clearly pointed out the historical difficulties in developing and marketing a sustained-release niacin product. After reviewing the Niaspan clinical data, the medical experts remained concerned about the safety and efficacy of sustained-release niacin. Indeed, Schering's own expert panel reported that this product, far from being straightforward, "need[ed] larger, longer studies and trials" and "compelling evidence" to support its safety and side-effect claims.[37]

- The marketing of a sustained-release nician product in Europe also wasn't straightforward. Because of the recent success of other cholesterol-reducing agents, principally the "statins," the market opportunity for a product such as Niacor-SR, according to one Schering Vice President, was "narrowing even prior to its introduction."[38] Other pharmaceutical companies which had considered and rejected a Niacor-SR license voiced similar concerns about the product's limited market potential.[39]

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[36] CPF 265-266, 272-284, 584, 588-595.

[37] CX 576 at SP 020711; *see also* CPF 281-284, 585, 596-609.

[38] CX 558 at SP 002720 (6/9/97 Martin Driscoll memorandum recommending discontinuation of negotiations for other sustained release niacin product); *see also* CPF 338, 616-617.

[39] CX 850 at USL 09089 (one company had no interest in Niacor-SR because "we do not expect that a product like Niacor can get a sufficient market share in Europe in the highly competitive segment of lipid lowering agents."); CX 857 at USL 09091 (another company had no

In addition, Schering certainly didn't have all the answers to the myriad questions presented by a sustained-release niacin drug, for the simple reason that it never asked the questions:

- Schering did not ask anything about the prospects for Niacor-SR's regulatory approval, including whether Upsher had solved its problemswith a crucial clinical study required for FDA approval (CPF 433, 468-470, 473-475, 655-658);
- Schering never examined the scope of Upsher's patent rights or whether Upsher even had the ability to license Schering to sell a once-a-day niacin product in Europe (CPF 434-436, 457-459); and
- Schering never inquired whether Niacor-SR would obtain the broad therapeutic labeling that it would need to compete successfully against other products of its type (CPF 430-431).

Schering's failure to seek the information needed to properly evaluate the Niacor-SR licensing opportunity further confirms that the $60 million was not for the Niacor-SR license, but rather for Upsher's agreement to stay off the market with its generic K-Dur 20 product. CPF 373-377, 660-663.

- ***The behavior of Schering and Upsher after execution of their agreement was inconsistent with their contention that they were serious about Schering's development of Niacor-SR***

The time schedule that was presented to the Schering Board of Directors for the development and marketing of Niacor-SR would have required the company to immediately mount an enormous effort to gain regulatory approval, manufacture, and market a new pharmaceutical. CX 338 at SP 12 00270, Memo of Board of Director's Presentation (June 24,

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interest in Niacor-SR because "[w]e are doubtful about the commercial prospects of a nicotinic acid based product in Italy, where this active ingredient is viewed as a somewhat outdated treatment."); CX 861 at USL 09096 (another company had no interest in Niacor-SR because "[t]he statins . . . are actually widely prescribed and there is not much room anymore for the nicotinic acids."); *see also* CPF 285, 586, 620-652.

1997). The evidence shows that Schering made no such effort. Although it had just committed $60 million cash to this project:

- Schering never established a "project team" to oversee the development and marketing of Niacor-SR (CPF 674, 679-680);
- The official purportedly "appointed" as the project leader had no idea he had been so appointed and found it "confusing" that his department would undertake these efforts since it was not responsible for seeking drug approval in Europe (CPF 676-678);
- Schering never submitted any filings to obtain European approval for Niacor-SR, never began the additional clinical trials that would have been necessary to make such filings, and never even received the clinical data from Upsher that would form the basis of these filings (CPF 692, 703-710); and
- Schering wasn't informed that Upsher had put the Niacor-SR project "on hold" until nearly nine months after the fact (CPF 711-716).

The parties' post-deal behavior (or lack thereof) confirms that neither Schering nor Upsher had a sincere interest in the development and marketing of Niacor-SR. CPF 664-670, 717-721.

- ***Schering was unwilling to make any non-contingent payment for another sustained-release niacin product that Schering believed was equal to or better than Niacor-SR***

The same year Schering agreed to make $60 million in up-front non-contingent payments to Upsher, purportedly in exchange for a license to Niacor-SR, Schering was unwilling to make any non-contingent payments for the rights to another sustained-release niacin drug, Niaspan. The undisputed facts concerning Schering's rejection of this similar opportunity are as follows:

- Niaspan was equal to or better than Niacor-SR, in terms of safety and efficacy as a drug, and was farther along in the regulatory approval process. CPF 736-763.

- Schering was offered the opportunity to license Niaspan outright in non-U.S. markets.[40] This non-U.S. license would have been available for a nominal up-front payment.[41] Schering preferred, however, to pursue rights to Niaspan in the United States. CX 540.

- Schering was unwilling to make any non-contingent payment for these U.S. rights to Niaspan.[42]

- Just days after Schering recommended cutting off negotiations for Niaspan, it agreed to pay $60 million in non-contingent, up-front payments for the non-U.S. rights to Niacor-SR.

Applying straightforward economic principles to these facts, Professor Bresnahan confirms that which should be obvious using basic common sense: Schering did not value the sustained-release niacin license as being worth $60 million in non-contingent payments, and therefore, Schering was willing to make this substantial payment only because it received something else of value – that is, Upsher's agreement not to challenge Schering's K-Dur 20 monopoly until September 2001.

- ***The Niacor-SR license does not stand on its own two feet, as respondents claim***

Respondents' principal defense of the $60 million non-contingent up-front payment – that the deal "stands on its own two feet" – hinges on the testimony of Mr. Hoffman, Schering's in-house counsel in charge of litigation and antitrust, and more specifically, the inference

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[40] CX 540 (2/11/1997 memo explaining the Niaspan opportunity to Schering management).

[41] Tr. 31:7650, 31:7655 (Patel) (the non-U.S. Niaspan rights were made available to AstraZeneca and Hoffmann-La Roche in return for a down payment of $5 million); Tr 31:7538-39 (Patel) (SmithKline-Beecham could have obtained the non-U.S. rights to a package of two drugs which included Niaspan in return for a down payment of around $10 million).

[42] CX 558 at SP 002719 (6/19/1997 memo recommending ending negotiations for Niaspan).

respondents need this Court to draw from that testimony. The testimony at issue is Mr. Hoffman's statement to Upsher during the settlement negotiations that "Schering was not going to be paying Upsher-Smith to stay off market." Tr. 15:3540-41 (John Hoffman).

It is hardly surprising that Schering would take such a bargaining position to get Upsher to lower its $80 million settlement demand. And by itself, such testimony would have no relevance to the antitrust issues presented here. Yet, respondents try to elevate this otherwise unremarkable testimony to their core defense. To make this defense work, however, they need this Court to ignore the rest of the evidence and rather infer that simply because respondents' lawyers purportedly were aware of the law prohibiting payments to keep one's competitors off the market, respondents must have obeyed that law. But as Your Honor correctly observed, where respondents fail, as they have here, to provide the "direct link" from the lawyers' statements to the client's behavior, that "formula" just doesn't add up. Tr. 12:2617-18.

Because respondents have chosen to maintain their attorney-client privilege, they offered no evidence to link Hoffman's statements to Schering's or Upsher's behavior. Without this evidence, we are all left wondering: Did Mr. Hoffman raise antitrust concerns with Upsher in order to get Upsher to lower its $80 million demand for payments, or because he believed it be an accurate assessment of the law? Respondents refused to answer on the basis of privilege. Did Hoffman tell his businesspeople about the antitrust risks of entering into settlements involving payment for delay? Schering won't say. Did the Schering and Upsher businesspeople actually listen to and follow the legal advice of their lawyers, assuming they were so advised? Did Hoffman take any action to prevent his client from entering into a settlement involving payment for delay? What did he do to make sure the payments to Upsher really were for the products

licensed? Did he monitor due diligence? Did he review the valuation? We'll never know because respondents have kept the best evidence of what was being said and done inside Schering and Upsher with respect to their lawyers' legal advice hidden behind claims of privilege.

Even where the evidence is not shrouded by privilege, it fails to support respondents' claim that the Niacor-SR licensing deal "stands on its own two feet." For example, far from being extraordinarily diligent in their evaluation of the Niacor-SR licensing opportunity, as would be expected where your lawyer has identified significant antitrust risks, Schering's due diligence efforts were remarkably superficial. *See* CPF 373-377, 660-663.

As further evidence, we need look no further than the memorandum to the Schering Board of Directors meeting where the proposed license agreement with Upsher was to be considered. One sentence (part of which is redacted) of that document recounts that Schering "informed them [Upsher] that any such deal should stand on its own merit." CX 338 at SP 12 00268. Even if Schering did not redact a key piece of this sentence, the document does not support the inference respondents would draw. For example, strikingly absent from this report is any assertion by Schering management to the Board that, based on its (abbreviated) review of the Niacor-SR project, the licensing deal did in fact stand on its own merit, independent of the patent settlement agreement. Indeed the document goes on to discuss the $60 million payments in the context of Upsher's demand for a "guaranteed income stream" to replace projected sales of generic K-Dur 20. CX 338 at SP 00270.

In short, respondents have offered no reason for this Court to infer, from Hoffman's bargaining position that the Niacor-SR licensing deal had to "stand on its own two feet," that the $60 million payment was for anything other than Upsher's agreement to stay out of the market.

B. Schering Paid AHP to Secure Its Agreement Not to Enter Until 2004

1. The terms of the agreement show payment for the entry date

On its face, Schering's settlement agreement with AHP shows it paid AHP $15 million as consideration for AHP's promise to abandon its challenge to Schering's patent and stay off the market until 2004. Para 3.1(a)(iii) provides:

> AHP and ESI each covenants that, in no event shall any or all of AHP, ESI, its or their Affiliates and/or any Acquired Businesses, taken as a group, prior to January 1, 2004, sell, offer to sell or market in the United States any Referencing Product [defined in Article I to include a potassium chloride product that is marketed by AHP as bioequivalent to K-Dur 20] . . .

CX 479 (6/19/98 settlement agreement) at SP 13 00075. Article IV, "Consideration," lays out the terms for Schering's payments to AHP: $5 million upon execution of the agreement and up to $10 million depending on the date AHP's ANDA product received tentative FDA approval.[43] Under the latter payment term, AHP got the full $10 million provided it obtained the requisite FDA approval by June 1999, and lesser amounts thereafter, a provision that by its terms reflects the link between the payment and AHP's potential lost revenues from agreeing to forestall entry.

Schering also agreed to pay AHP $15 million in non-contingent payments - over and above conventional royalties based on sales – under a separate licensing agreement for European marketing rights to two AHP generic products unrelated to the patent litigation. CX 480 at SP 15 00069-70. While these substantial non-contingent payments for rights to two generic products

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[43] CX 479 at SP 13 00078. *See* CPF 880.

raise questions, the existence of the $15 million in direct payments for the settlement agreement obviates any need to undertake an inquiry into whether the licensing payment was additional consideration for the 2004 entry date. Schering's payment of at least $15 million to secure AHP's agreement not to compete with K-Dur-20 until 2004 is sufficient to constitute an antitrust violation.

The written contract between Schering and AHP plainly shows an agreement to pay millions of dollars in exchange for a promise not to compete. The payment keyed to the date of FDA approval in particular shows, as Mr. Hoffman conceded, that this term tied the amount of payment to how quickly AHP was able to bring a generic K-Dur 20 product to market. Tr. 12:2646 (John Hoffman).

2. The evidence shows that Schering and AHP acted on their incentives to delay generic entry

A variety of evidence beyond the agreement itself confirms that Schering paid AHP to stay off the market. First, as in the case of Upsher, the record shows that both parties were aware that Schering had strong incentives to pay AHP to avoid a negative result in the patent litigation, that is, the patent protection for K-Dur 20 was narrow and the loss to Schering from AHP's entry would far exceed what AHP could hope to earn by launching its product.[44] Furthermore, Schering's incentives to pay AHP to settle increased as the litigation progressed.

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[44] • ; CPF 823-840 (patent protection); CPF 859 (AHP demand for $100 million based on Schering's lost profits); 860 (Rule testimony that payment based on brand's loss would be much greater than one based on generic's gain); CPF 1174, 1182.

At a January 1998 hearing before the trial judge to determine the scope of the patent (the "Markman hearing"),[45] the judge indicated he had significant questions about the merits of Schering's infringement argument.[46] Indeed, the evidence of the views expressed by the trial judge directly contradicts a fundamental premise of Schering's defense of the AHP settlement: that the parties reached a settlement after AHP's defense in the patent case had "collapsed."[47] Schering settled with Upsher on the eve of trial, but in the case of AHP there had been no particular urgency to settle. Once the court indicated that it did not share Schering's view that it had a "slam dunk" case,[48] however, the stakes were raised. A court decision construing the patent claims narrowly, or holding that a broad construction of those claims would render the

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[45] The first step in analyzing a claim of patent infringement is to construe the claims specified in the patent. The Supreme Court made it clear that it is the job of the court, not the jury, to construe the patent claims in *Markman v. Westview Instruments*, 517 U.S. 370 (1996) and the hearing held by the court to hear evidence relating to claim construction has become known as a Markman hearing. Tr. 15:3326-27 (Miller).

[46] Tr. 15:3387-89 (Miller) (acknowledging judge's statements in transcript raising questions about Schering's position, such as "this is far from a clear issue," and agreeing that judge indicated that he was concerned that Schering's patent would be invalid if it were read as broadly as Schering claimed it should be read). *See also* Tr. 14:3038-39 (Banker) (testimony regarding same portion of Markman hearing transcript).

[47] *Respondent Schering-Plough Corporation's Pretrial Brief* (January 15, 2002) at 2 ("ESI's defense in the patent case had collapsed"), 10 ("at the time of the settlement, ESI had no viable defense to Schering's infringement claims"), 22 ("Schering unquestionably would have won. ESI's defense had completely collapsed."). To rebut Schering's claims about the supposed weakness of AHP's defense in the infringement case, complaint counsel offered testimony from a technical expert, Dr. Umesh V. Banakar, who concurred with the opinions of AHP's expert at the Markman hearing, and disagreed with those of Schering's expert, Dr. Banker. *See* Tr. 26:6387-92 (Banakar).

[48] Tr. 14:3038-39 (Banker); 15:3387-89 (Miller) (acknowledging that the judge's statement in the transcript of the Markman hearing so stated).

patent invalid, could have had significant implications for Schering's ability to enforce its patent against any potential generic entrant.

In addition, legal developments concerning the 180-day exclusivity period granted to first ANDA filers under the Hatch-Waxman Act created additional uncertainty as to whether Schering's agreement with Upsher would block AHP's entry, increasing the threat posed by AHP.[49] This was true because Upsher might be deemed to have lost its eligibility for the exclusivity period, and also because the FDA had begun to take the position that the exclusivity period could be triggered by a court decision involving another company's ANDA product that held the patent was not infringed.

Evidence concerning the negotiations that preceded the agreement also confirms that the parties agreed to exchange payment for a promise not to compete. Contemporaneous documents created by the parties during the negotiations show that Schering's first settlement proposal was that AHP abandon its generic K-Dur 20 product entirely, and instead receive compensation from Schering for promoting K-Dur 20.[50] This approach would have, in effect, compensated AHP for keeping its product off the market permanently.[51] Thus, from the outset Schering was willing to offer payment to eliminate the potential competition from AHP.

AHP rejected Schering's proposal and suggested instead that Schering "make an appropriate payment" to AHP, and in return AHP would "forebear from entering the market"

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[49] *See* discussion at section I.C.; CFP 911-922.

[50] CX 459; CX 466.

[51] Tr. 12:2662 (John Hoffman) (Schering offer would have involved a complete abandonment of the ESI product).

until "some subsequent time (for example, in 2002)."[52] The negotiations over the payment focused on the concept of Schering compensating AHP for revenues lost as a result of agreeing to stay off the market:

- During an August 1997 settlement conference, Schering counsel Mr. Rule expressed the view that a payment based on the revenues lost by AHP agreeing not to come to market would be "more defensible" than one based on a share of Schering's profits. Tr. 11:2584 (Rule). This shows that Schering wasn't flat-out refusing to consider a settlement involving a payment to AHP to stay off the market. Far from it, Mr. Rule's statement suggests the approach the parties took in calculating that payment.[53]

- Shortly thereafter AHP provided Schering with estimates of what it would lose by staying off the market for several years. *See* CX 461.

- From AHP's perspective, in evaluating "the economics of the settlement proposals," it needed to consider when it would be entering relative to other generics.[54] Assumptions about the order of generic entry would significantly affect the calculation of lost revenues.[55]

- AHP would have no lost revenues, however, if its ANDA product never got FDA approval. During negotiations, Schering stressed its need to know whether AHP had a product that would receive FDA approval, and demanded and received assurances that AHP's product was approvable.[56]

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[52] CX 458 at C&B-2 002179; *see also* CX 459.

[53] Neither respondent in this proceeding has claimed that the legality of the payment turns on whether it is calculated based on the generic's lost revenues or a percentage of Schering's profits.

[54] CX 462 at AHP 10 01670.

[55] *See* CX 461 at SP 13 00004 (AHP estimates of lost revenues based on assumption that AHP, Upsher, and Warrick (Schering's generic) launch their products simultaneously); CPF 816-820.

[56] *See* CX 468 at AHP 05 00226 (Schering would not make another settlement proposal until it could review AHP's correspondence with the FDA so that it could determine whether AHP had a product that was approvable); CX 469 (summary of AHP's correspondence with the FDA); CX 474 at SP 13 00633 (payment schedule "reflects the central importance of ESI's

- The parties did not negotiate the $5 million up-front payment as compensation for attorneys fees.[57]

AHP persisted in its demand that it be paid in return for an agreement not to enter the market. CPF 858. Indeed, there appears to be no dispute that AHP held firm to its demand that it be paid for any agreement to an entry date in the future.[58]

By September 1997, AHP knew that Schering had agreed to make large up-front cash payments in its settlement with Upsher.[59] Following Upsher's lead, AHP refused to settle the litigation until Schering agreed to pay AHP as well. Tr. 12:2720-21 (Driscoll). Schering's attempt to argue that the payment was not for the entry date – on the ground that the parties agreed to the date well before Schering agreed to make the $15 million payments – ignores the simple fact that AHP did not agree to the 2004 date absent the payment.

Thus, the evidence as to Schering's incentives and the record of the parties' negotiations leading up to the agreement confirm what appears directly on the face of the document.

3. Schering's defense to the AHP agreement requires it to walk away from the contemporaneous documents

At trial, Schering made various attempts to dismiss the significance of the terms of the written agreement that show the payments not to compete. Mr. Nields repeatedly claimed that

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representations" that Micro-K 20 was approvable)

[57] Mr. Hoffman testified that the magistrate judge had suggested that the $5 million could be viewed as paying AHP its legal fees (Tr. 12:2620, 2622) (John Hoffman), but Hoffman declined to characterize them in that manner, and stated that Schering had no information from AHP that its attorneys fees amounted to $5 million. Tr. 12:2643-44 (John Hoffman).

[58] *See, e.g*, Tr. 12:2658 (John Hoffman).

[59] CX 463; 464 (summary of Key-Upsher settlement agreement).

trial testimony by Schering representatives about the negotiations was essential to determine what the parties actually agreed to.[60] The terms of the written contract are unambiguous, however, and in any event, key claims made by these witnesses do not withstand scrutiny.

First, Schering attempted to dismiss the significance of the $10 million payment tied to FDA approval of AHP's ANDA through Mr. Driscoll's testimony that, at the time of the agreement, he did not believe Schering would ultimately have to pay it. This testimony, however, is belied by more reliable contemporaneous documents. Correspondence by Schering's counsel leading up to the final settlement agreement expressly states that, in reaching the January 1998 agreement in principle, Schering relied on AHP representations that its ANDA was approvable. CX 474 at SP 13 00633 (the payment schedule "reflects the central importance of ESI's representations" that Micro-K 20 was approvable).[61] In addition, testimony of Mr. Dey of AHP, who was heavily involved in the settlement negotiations, is consistent with this document,

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[60] *See* Tr. 11:2501, 2502, 2508-09, 2511, 2517 (Nields).

[61] The June 17, 1998 letter from Schering outside counsel to counsel for AHP states that prior to the January 1998 settlement, AHP representatives, Messrs. Heller, Dey, and Alaburda, represented that AHP's generic product was approvable and that FDA concerns that the supporting data was too old "would be resolved easily and promptly." CX 474 at SP 13 00633. It goes on to state:

> Item II of the statement of settlement principles drafted by Paul Heller (copy attached) made it clear that the $10 million (declining) payment to ESI would turn on FDA approval of Micro-K 20. Schering also made it clear that the FDA approval of Micro-K 20 was an essential component of the principles of agreement, and the payment schedule in item II reflects the central importance of ESI's representations.

CX 474 at SP 13 00633.

and states that in his view Schering would not have settled the litigation if it believed that AHP did not have a product capable of obtaining FDA approval. CPF 856.

Other contemporaneous documents show that Schering sought and received assurances that AHP had an approvable product. For example, in November 1997, Mr. Herman, outside counsel to Schering in the patent litigation, took the position that "Key is unwilling to make another settlement offer until ESI demonstrates that it has a bona fide 20 mEq potassium chloride product that, but for this lawsuit, would receive FDA approval." CX 468 at AHP 05 00226. AHP subsequently provided him with correspondence between ESI and the FDA concerning the ANDA,[62] and thereafter, in December 1997, Mr. Herman made a new settlement proposal to AHP. CX 470.

AHP responded with a counter-proposal that included a provision calling for $50 million in payments from Schering to AHP "upon the issuance by the FDA of an approvable letter for ESI Lederle's ANDA." CX 473, CX 471. Schering did not accede to this provision, however, and ultimately agreed to pay only $10 million, and only if AHP gained approval within a specific time frame. CX 472, 474, 479. Negotiation over the amount of payment would have been unnecessary if Schering truly thought AHP – a large corporation with no shortage of resources and ample incentives to obtain FDA approval – stood no chance of gaining that approval.[63]

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[62] CX 469; Tr. 11:2522-23 (Herman).

[63] Although Mr. Driscoll repeatedly asserted that at the time he did not think AHP had an approvable product, this was evidently not based on any hard evidence that would permit him to confidently make a $10 million gamble, because he testified that this was merely "my assumption" based on AHP's behavior during the negotiations. CX 1494 at 127-28 (Driscoll IH).

Second, as with the Upsher agreement, Schering offered testimony that its lawyers stated during the negotiations that Schering, citing antitrust concerns, would not pay a competitor to stay off the market.[64] As Your Honor has properly recognized, however, these statements cannot support an inference that Schering acted in accordance with those statements.[65] We have no way to test the statements in order to determine whether Schering was simply posturing as part of the negotiating process in order to strike a better deal, or whether the attorneys' confidential advice to the client was consistent with these statement to third parties. And in fact, in the end Schering entered into a written agreement with AHP which on its face shows payments to be made by Schering in consideration for AHP's promise to stay off the market.

Finally, Schering attempts to walk away from the plain language of its agreement with AHP by suggesting that it was coerced into the agreement by the magistrate judge or the trial judge – or that Schering acted on a belief that it was being threatened by these court officials. For example, Mr. Herman, Schering's outside counsel in the patent case, testified that the trial judge ordered him to stay in the courthouse until the case was settled. Tr. 11:2530. Mr. Driscoll testified that the magistrate judge told him that the trial judge had ordered him to get a settlement (Tr. 12:2703-04), and used threats to force the settlement (Tr. 12:2714).

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[64] *See* Tr. 12:2606 (Mr. Nields states "We are introducing in both cases evidence that Schering declined to pay for delay, citing antitrust concerns.").

[65] *See* Tr. 12:2617-18:

> Judge Chappell: And your argument is that respondents are going to try to make the case that this witness told a judge something, and then there's supposed to be some implication that the client did something based on that without . . . proving to me the direct link to the client? . . . I don't think that adds up, Mr. Orlans, and I'll tell you that right now and I'll tell them right now."

Testimony regarding statements allegedly made by the magistrate and the trial judge was the subject of numerous objections at trial, and was admitted only on a limited basis and not for the truth of the matters asserted. More importantly, to credit these claims, Your Honor would need to find that two judicial officers went beyond merely encouraging settlement, and engaged in improper judicial behavior, in effect threatening to deny Schering its right to an impartial adjudication.

Mr. Herman conceded on cross-examination, however, that the transcript of the Markman hearing shows the trial judge: (1) expressing his desire to hear closing arguments and willingness to "remain this evening as long as it takes to finish this matter." (Tr. 11:2551); (2) agreeing to a request from the parties that he defer closing arguments to enable them to pursue settlement discussions (Tr. 11:2551-52); and (3) stating "if we don't settle the case, I want to conclude the Markman hearing with closing arguments tomorrow." (Tr. 11:2554).[66] These statements hardly portray a judge unwilling to move forward with the case or forcing the parties to settle. Although Mr. Herman repeatedly claimed that the trial judge "often said one thing on the record and another thing privately in chambers" (Tr. 11:2552; *see also* 11:2549; 2553-54), the normal practice of the Commission and the courts is to rely on contemporaneous documents over self-serving trial testimony.[67] That principle is particularly appropriate here, given the

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[66] *See also* Tr. 11:2548 (Mr. Herman testifying that he recalled the trial judge offering to hold oral arguments on the Markman hearing on Saturday in order to permit the parties to engage in settlement discussions on Friday).

[67] *See, e.g., United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1948); *Adolph Coors Company*, 83 F.T.C. 32, 326 (1973) ("It is well established, however, that little weight can be given to testimony which is in conflict with contemporaneous documents, particularly when the crucial issue involves mixed questions of law and fact.").

nature of the accusations that Schering's witnesses have leveled at two judicial officers who are not present to defend themselves.

Moreover, Schering's suggestion that it believed it had no option to pursue the litigation is untenable.[68] Schering was represented by experienced counsel, who were participating in a voluntary process of non-binding mediation presided over by a magistrate judge.[69] Judges routinely encourage litigants to settle. But forcing a settlement on unwilling litigants is another matter entirely.[70] Schering's Associate General Counsel, Mr. Hoffman, acknowledged that where parties cannot agree on a settlement the judge must try the case. Tr. 12:2647-48. Furthermore, Mr. Hoffman admitted that the magistrate never said that a party who did not settle would be penalized. Tr. 12:2648. Thus, even if Schering counsel believed they were being pressured by the magistrate to settle, it is implausible that Schering believed it could not litigate the case if it deemed any proposed settlement with AHP undesirable.[71]

In sum, the terms of the written agreement show Schering paid AHP at least $15 million to secure an agreement to stay off the market for six years. Evidence concerning the negotiations

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[68] It also is inconsistent with Schering's argument that it would have won the patent litigation against AHP.

[69] *See* SPX 73 (10/16/96 letter from Schering counsel to Hon. Jan DuBois, with Mr. Herman advising that both plaintiff and defendant "have agreed to participate in non-binding mediation.").

[70] *See, e.g., Newton v. A.C. & S., Inc.*, 918 F.2d 1121, 1129 (3d Cir. 1990) ("[T]he court's efforts to expedite the settlement of cases . . . should not unduly pressure or coerce litigants into settlement.").

[71] *See, e.g., Brooks v. Great Atlantic & Pacific Tea Co.*, 92 F.2d 794, 796 (9th Cir. 1937) ("The judge must not compel agreement by arbitrary use of his power and the attorney must not meekly submit to a judge's suggestion, though it be strongly urged.").

confirms what appears is apparent from the agreement. The self-serving testimony of Schering representatives offered in an attempt to offset the clear terms of the agreement is contradicted by more reliable evidence in the record, and should be given no weight.

III. THE AGREEMENTS ARE UNLAWFUL HORIZONTAL RESTRAINTS

A. The Legal Framework for Analysis of Horizontal Restraints

The FTC Act's prohibition on "unfair methods of competition" encompasses violations of other antitrust laws, including Section 1 of the Sherman Act, which prohibits agreements in restraint of trade.[72] Agreements between competitors or potential competitors that govern the way they compete with one another are horizontal restraints of trade.[73] Schering's agreements – with two companies that were seeking to market low-cost generic products that would compete with Schering's K-Dur 20 potassium supplement – are thus horizontal restraints. Such restraints are unlawful if they "unreasonably" limit competition.[74]

The antitrust inquiry into the reasonableness of a horizontal restraint turns on the competitive significance of the conduct in question. The courts begin by asking whether the conduct appears to be a practice that would "always or almost always tend to restrict competition and decrease output" or instead is "designed to 'increase economic efficiency and render markets more, rather than less, competitive.'" *Broadcast Music, Inc. v. CBS*, 441 U.S. 1, 19-20 (1979)

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[72] *See FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 454 (1986) [hereinafter *IFD*].

[73] *See, e.g., NCAA v. Board of Regents of the Univ. Of Okla.*, 468 U.S. 85, 99 (1984) [hereinafter *NCAA*].

[74] *Chicago Bd. of Trade v. United States*, 246 U.S. 231 (1918); *National Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679 (1978).

("BMI"). When the anticompetitive character of the restraint is clear, the restraint is deemed *per se* unreasonable.[75]

Where there is a plausible justification for the restraint, or where the anticompetitive character of the restraint is less obvious, then a closer look is needed to assess its likely competitive effects.[76] But, the purpose of the inquiry remains the same: to form a judgment about the competitive significance of the restraint. As the Supreme Court observed in *National Society of Professional Engineers v. United States*, 435 U.S. 679, 688 (1978), the antitrust inquiry under the rule of reason "does not open the field . . . to any argument in favor of a challenged restraint that may fall within the realm of reason." Thus, parties may not justify harm to competition by claiming that the result that obtained was "reasonable."

The extent of scrutiny needed to assess the competitive significance of the restraint under the rule of reason will vary, depending on the nature and character of the conduct in question and the strength of the justification offered.[77] As the Supreme Court explained in its most recent horizontal restraints case, *California Dental Association v. FTC*, 526 U.S. 756, 780-81 (1999):

> [T]here is generally no categorical line to be drawn between restraints that give rise to an intuitively obvious inference of anticompetitive effect and those that call for more

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[75] *See, e.g., FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411 (1990).

[76] *General Leaseways, Inc. v. National Truck Leasing Ass'n*, 744 F.2d 588, 595 (7th Cir. 1984) ("The *per se* rule would collapse if every claim of economies from restricting competition, however implausible, could be used to move a horizontal agreement not to compete from the *per se* to the Rule of Reason category.").

[77] *See, e.g., NCAA*, 468 U.S. 85; *IFD*, 476 U.S. at 461-62 (dentists' agreement to withhold x-rays from insurers was sufficiently likely "to disrupt the proper functioning of price-setting mechanism of the market" to be condemned without proof that the conduct actually resulted in higher prices).

detailed treatment. What is required, rather, is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint.

Respondents' legal defense of their challenged conduct rests heavily on the premise that the legality of the agreements depends on whether they can be labeled *per se* unlawful. In this case, the distinction is irrelevant. Regardless of how detailed the inquiry, whether judged under a *per se* standard or under a more extensive examination under the rule of reason, the evidence establishes a violation.

Accordingly, we first set forth the legal analysis under the rule of reason.

- Is the nature and character of the restraint inherently anticompetitive? (B.1)
- Is there a sound theoretical basis that explains why the restraint is likely to result in significant anticompetitive effects? (B.2)
- Does the record evidence support a finding that the restraint was likely to result in significant anticompetitive effects in this case? (B.3 & B.4); and
- Have respondents come forward with cognizable procompetitive justifications to offset the demonstrated anticompetitive effects of the restraint? (B.5)

Finally, we address why the agreements are also properly condemned as *per se* unlawful horizontal restraints.

B. The Challenged Agreements Are Unlawful Under the Rule of Reason

At issue here are two agreements under which potential generic entrants received payments of tens of millions of dollars in connection with settlement of charges of patent infringement brought against them by Schering, and in consideration of their agreement not to market until a date several years in the future.

- The nature of the restraint – a payment to a potential competitor to secure an agreement not to enter and compete – is, on its face, inherently anticompetitive.

- While the date the generics otherwise would have entered is uncertain, economic theory explains why the agreements are likely, absent some justification, to result in later generic entry than would otherwise be expected.

- The record evidence shows that respondents acted on these incentives, and that clear anticompetitive effects flow from delaying generic competition.

- And respondents have failed to come forward with any plausible procompetitive justifications.

As a result, Schering's agreements with Upsher and AHP constitute unlawful horizontal restraints under the rule of reason.

1. The nature of the agreement: Paying a potential competitor to withhold competition is inherently anticompetitive

Paying a party to stay off the market directly restrains competition on price and output, and is a classic restraint of trade.[78] "Restrictions on price and output are the paradigmatic examples of restraints of trade that the Sherman Act was intended to prohibit." *NCAA*, 468 U.S. at 107-08. Such restraints have obvious anticompetitive effects even where they involve uncertain competition, and even where that uncertainty is related to patent litigation.

In *Palmer v. BRG*, the Supreme Court made clear that agreements not to compete among potential competitors are as unlawful as those between firms that are current competitors at the time the agreement is entered into. *Palmer*, 498 U.S. at 48-50. Professor Hovenkamp points out that in many cases one of the parties to a non-compete agreement may be uncertain as to the likelihood of entry by the other, and wishes to have "insurance" against such entry. As *Palmer*

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[78] *See, e.g., United States v. Addyston Pipe & Steel Co.*, 85 F. 271 (6th Cir. 1898) (Taft, J.), *aff'd*, 175 U.S. 211 (1899); *United States v. Masonite Corp.*, 316 U.S. 265 (1942) (potential infringers withdrew their products from the market and received payment through a price-fixing agreement); *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990) (competitors agreed not to enter each other's territories and to share profits from sales in one of those territories).

reflects, however, "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." Herbert Hovenkamp, XII *Antitrust Law* ¶ 2030b at 175 (1999).

Uncertainty in the pharmaceutical industry may stem from a variety of factors, including the potential competitor's ability to successfully manufacture the product or obtain regulatory approval, or its chances of prevailing in a patent infringement challenge. Regardless of the source of this uncertainty, however, a payment to purchase protection from uncertain competition raises similar concerns.[79] Such factors may influence a plaintiff's ability to prove damages, but do not alter the analysis of liability.[80] Even though the payment may arise in the context of uncertain patent litigation, a patent does not vest its owner with the unfettered right to bribe competitors to abandon their competition.

The Supreme Court's decision in *United States v. Masonite* illustrates this point.[81] In that case, Masonite, the patent-holder, sued or threatened to sue its competitors for patent infringement. To resolve these disputes, Masonite licensed the competing firms to sell its product, but at a price that it set. 316 U.S. at 267-73. In its decision, the Supreme Court

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[79] From an economic perspective, Professor Bresnahan testified that it would clearly be anticompetitive for an incumbent to pay a potential generic rival to defer entry until a specific date in the future, even if the generic's ability to obtain FDA approval was uncertain. Tr. 34:8085-86. And, Professor Bresnahan explained that, as an economist, there would be no reason to treat uncertainty due to patent litigation any differently. Tr. 34:8087.

[80] *See, e.g., United States v. Microsoft*, 253 F.3d 34, 79-80 (D.C. Cir. 2001) (per curiam) (distinguishing liability and remedy); *Microbix Biosys., Inc., v. BioWhittaker, Inc.*, 172 F.Supp. 2d 680, 694-95 (D. Md. 2000), *aff'd on other grounds*, 2001 WL 603416 (4th Cir. 2001) (distinguishing damages inquiry from the assessment of competitive effects for purposes of assessing liability under the rule of reason).

[81] *See United States v. Masonite Corp.*, 316 U.S. 265 (1942).

expressly assumed that the patents were valid and that the competitors had tried unsuccessfully to develop non-infringing products. *Id.* at 276, 280-81. Nonetheless, the Court still found that the license arrangements went beyond Masonite's legitimate rights and constituted illegal price-fixing. The Court explained that Masonite's licensing scheme had enticed its competitors to abandon their own products and patent challenges in exchange for a share of the patent-holder's profits. *Id.* at 282-83.[82]

Like the price-fixing in *Masonite*, Schering's payments here provided the inducement to the generic firms to lessen their competitive vigor. By paying its potential generic rivals a share of the profits, Schering induced them to forgo their patent challenges and to stay off the market until a date years in the future. "Active and vigorous competition then tend[ed] to be impaired, not from any preference of the public for the patented product, but from the preference of the competitors for a mutual arrangement for price-fixing which promises more profit if the parties abandon rather than maintain competition." *Id.* at 281.[83]

Thus, the crux of the antitrust claim is, as one court put it, the "right to a market in which manufacturers and distributors of generic drugs [make] their decisions about challenging patents and entering markets free from the influence of cash payments amounting to unreasonable

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[82] *See also In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 2d 740 (E.D.N.Y. 2001) ("Cipro") (rejecting the argument that the existence of a valid patent forecloses the possibility of antitrust effects flowing from the agreement).

[83] *See also U.S. v. Singer Mfg. Co.*, 374 U.S. 174 (1963) (finding patent interference settlement unlawful under the antitrust laws without reaching the substantive merits of the patent claim); *U.S. v. New Wrinkle Inc.*, 342 U.S. 371 (1952) (finding a licensing agreement in violation of the Sherman Act even though the agreement settled a patent interference litigation); *U.S. v. Line Material Co.*, 333 U.S. 287 (1948) (finding licensing agreements in violation of the Sherman Act without discussing invalidity or infringement).

restraints of trade." *Cipro* 166 F. Supp. 2d at 749. Recognizing that this practice of paying a generic drug manufacturer not to market its product interferes with this right, courts have found the restraint to be *per se* illegal.[84]

The *Cardizem* and *Terazosin Hydrochloride* cases involved agreements arising in the context of patent litigation. In each of those cases, as here, the brand-name pharmaceutical company paid the potential generic entrant not to enter the market. Each court reached the same basic conclusion: a payment to a potential, but uncertain competitor, was "a straight forward horizontal market allocation agreement and thus fits within the category of business practices which have long been held illegal *per se* under section 1 of the Sherman Act."[85] The courts rejected the claim that, because the companies were not actual competitors, the agreement was not horizontal, holding that it was sufficient to show that the parties were potential rivals, and that potential rivalry was eliminated to establish a horizontal market allocation.[86] And the *Cardizem* court dismissed an argument, similar to the one advanced by respondents here, that the agreement was procompetitive because it included a license which guaranteed the generic's

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[84] *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, 706-07 (E.D. Mich. 2000), *appeal docketed*, No. 00-2483 (6th Cir. Dec. 19, 2000) (concerning the Hoechst/Andrx agreement); *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340, 1349 (S.D. Fla. 2000) (concerning the Abbott/Geneva/Zenith agreement); *see also Eon Labs Mfg., Inc. v. Watson Pharm., Inc.*, 164 F. Supp. 2d 350, 356 (S.D.N.Y. 2001) (finding such a restraint to be "highly suspect").

[85] *Cardizem*, 105 F. Supp. 2d at 701; *see also Terazosin Hydrochloride*, 164 F. Supp. 2d at 1349 (quoting *U.S. v. Topco Assoc., Inc.*, 405 U.S. 596, 608 (1972)) (characterizing the Abbott/Geneva/Zenith agreements as an "agreement[s] between competitors at the same level of the market structure to allocate territories in order to minimize competition").

[86] *Cardizem*, 105 F. Supp. at 700; *Terazosin Hydrochloride*, 164 F. Supp. 2d at 1349.

ability to enter well before patent expiration regardless of whether the generic's product was found to be infringing. *Cardizem*, 105 F. Supp. 2d at 705-06.[87]

Because the "great likelihood of anticompetitive effects" from the settlement agreements in this case "can easily be ascertained," the agreements can be summarily condemned, unless respondents offer a plausible procompetitive justification.[88] As we next explain, the conclusion that the agreements at issue are anticompetitive rests on far more than the presumption of harm from paying a competitor not to compete.

2. The economic incentives of the parties support a finding that the likely purpose and effect of Schering's payments to its generic competitors was to delay generic entry

Economic analysis explains *why* Schering's payments to its potential generic rivals are likely, absent some justification, to result in later generic entry than would otherwise be expected.[89] The effects of generic entry on consumer prices are well-documented. Generic entry causes prices to fall dramatically, which benefits consumers. Empirical research has shown that the first generic to enter is typically priced 25 percent or more below the branded drug's retail price. As additional generics enter the market over time, the price of generic drugs continues to

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[87] The D.C. Circuit in *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 811 (D.C. Cir. 2001), considered the HMRI/Andrx agreement in a different context and noted that the alleged agreement "could reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions."

[88] *California Dental Ass'n*, 526 U.S. at 770.

[89] The Commission may rely on economic theory and common sense as well as record evidence to determine whether a particular restraint harms competition. *See IFD*, 476 U.S. at 456.

fall, sometime to less than 50 per cent of the branded price.[90] It is also well understood in the pharmaceutical industry that when generic entry does occur, it quickly takes market share away from its branded counterpart. As a result, the incumbent branded drug company suffers a rapid and steep decline in sales and profits. Because generic drugs are priced so much lower than the branded drug, the returns to the brand name company from extending its monopoly will almost always exceed the potential economic gains to the generic applicant.

These market realities explain the incentive and ability of the incumbent to pay the would-be generic a share of its profits to withdraw its patent challenge and forestall entry (Tr. 3:527-30 (Bresnahan)), and explain why the generic has the incentive to accept such an arrangement. In the absence of a payment, a settlement or decision not to settle implicitly reflects each party's expectations about the outcome of the litigation. Payments to the generic entrant necessarily alter the competitive relationship of the parties, aligning their interests and distorting the generic firm's previous incentive to compete. The parties can always be made better off by preserving and sharing the brand's profits. We can confidently predict that the payment will result in an entry date that is later than both parties expected from the litigation or than would occur in a settlement without a payment.

3. The record evidence confirms that the restraints are likely to produce significant anticompetitive effects and that the parties had the power to affect market-wide competition

The evidence demonstrates the likely anticompetitive effects of Schering's payments to its potential competitors that economic theory predicts. Generic entry would (and did) offer

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[90] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998) at xii.

consumers the same product at a substantial discount; delaying such an option harmed consumers. As a result, entry by a generic K-Dur 20 product, whether by Upsher or AHP, would have (and eventually did) cause Schering to lose substantial sales and profits. Schering's lost profits dwarfed the expected profits that either entrant expected. Even though generic entry was uncertain, Schering and its would-be generic rivals would earn greater profits if the generics accepted a share of Schering's profits to stay-off the market. *See* Tr. 3:531-33 (Bresnahan).

Not only were the incentives to delay generic entry clear, the parties acted on these incentives. The evidence from respondents' own testimony about the negotiations that led to the agreements, as well as the contemporaneous business documents, is far more consistent with an agreement to share profits than, as they assert, an agreement to license products. In the case of Upsher, the evidence shows:

- Upsher negotiated for compensation to stay out of the market;
- Schering concluded that compensating Upsher for staying out of the market was "a prerequisite to any deal";
- Schering and Upsher both realized that generic entry would harm Schering more than it would benefit Upsher;
- In the "Executive Summary" – the blueprint for Schering's negotiations – Schering estimated Upsher's forgone generic K-Dur 20 revenues and eventually agreed to pay an amount equal to these estimates;
- The Executive Summary shows that Schering planned to pay Upsher for its lost revenues only so long as Schering maintained its monopoly;
- At the time the parties were negotiating the $60 million price tag, neither Schering nor Upsher had any basis to believe the licensed products had substantial value; and

- The resulting agreement contains a broad ban on competing with any generic version of K-Dur 20, not merely the allegedly infringing product that was the subject of the patent litigation.[91]

Taken together, this evidence shows that Schering and Upsher understood that Upsher's entry would harm Schering's profits, that Schering would lose more than Upsher would gain, and that the parties would be better-off avoiding competition and sharing the profits. *See* Section II.A.

The evidence on the AHP agreement is equally compelling.

- Both parties predicted generic entry would harm Schering more than it would benefit AHP;
- As time progressed, the incentives for delay increased as the uncertainty regarding the 180-day exclusivity made it more likely that AHP could enter prior to Upsher and, during the Markman hearing, the judge expressed views on the merits that were less optimistic than Schering's own view;
- Although Schering claims it would not pay for delay, Schering offered to pay AHP to withdraw completely from the market;
- AHP demanded a payment to stay off the market, justifying the amount of the demand based on the damage AHP's entry would inflict on Schering's profits;
- The agreement itself explicitly conditioned the payment on AHP's agreement not to market a generic K-Dur 20 product, and tied the amount of the payment to the date AHP would receive approval. In other words, the earlier AHP would be a threat to Schering's monopoly, the more money AHP would receive;
- The resulting agreement contains a broad ban on competing with any generic version of K-Dur 20, not merely the allegedly infringing product that was the subject of the patent litigation. *See* Section II.B.

In sum, this evidence shows (1) the foundation for a well-accepted economic theory about Schering's ability and incentive to delay generic competition and the incentive of the potential

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[91]Tr. 3:536-40 (Bresnahan) (provisions consistent with parties acting on incentives to delay entry).

generics rivals to accept such an arrangement, (2) proof that the conditions of that theory applied in the K-Dur 20 market, and (3) proof that the parties were acting on those incentives. In addition, the fact that respondents' stated justification for the $60 million payment to Upsher – that it was in consideration for licenses to Niacor-SR and four other insignificant products – is a pretext (*see* Section II.A), provides a further basis to infer that the conduct was anticompetitive.[92]

This evidence is far more than was needed by the Supreme Court to condemn the restraints in *Indiana Federation of Dentists*. Not only are the challenged restraints at issue here more obviously anticompetitive than in *IFD*, the evidence of their actual impact on competition is more substantial. In *IFD*, the Court considered an agreement among dentists to refuse to provide x-rays to insurers seeking to evaluate insurance claims. Although declining to apply the *per se* rule, a unanimous Court found "no elaborate industry analysis" was needed to show "the anticompetitive character of such an agreement." 476 U.S. at 459. It rejected the Seventh Circuit's holding that the Commission lacked adequate record evidence to support its finding that the conspiracy had the effect of suppressing competition among dentists with respect to their cooperation with the requests of insurers, noting the Commission could reasonably rely on common sense and economic theory as well. *Id.* at 456. Because the conduct was "likely enough to disrupt the proper functioning of the price-setting mechanism of the market," the Court could conclude the practice was anticompetitive without proof that the conduct "resulted in higher

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[92] *See Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.*, 472 U.S. 284, 296 n.7 (1985); *JTC Petroleum Co. v. Piasa Motor Fuels, Inc.*, 190 F.3d 775, 778-79 (7th Cir. 1999) ("The combination of the price difference with the evidence of pretext supports an inference that the producers were being compensated by the applicators for shoring up the cartel.").

prices . . . than would occur in [the conduct's] absence." *Id.* at 461-62. Since the Federation had advanced "[n]o credible argument" that the restraint had procompetitive effects, it was unlawful. *Id.* at 459.

Following the Supreme Court's reasoning in *IFD*, the "anticompetitive consequences of this arrangement are apparent." *NCAA*, 468 U.S. at 106. Whereas the restraint in *IFD* limited the information consumers use to make purchasing decisions, Schering's payments to Upsher and AHP deprived consumers access to a competing product by inducing them to abandon their patent challenge and to accept an entry date many years in the future. These payments, thus, delayed competitive entry compared to what the parties expected under litigation or to any other settlement they could have reached. The direct evidence of the effect of generic entry on the sales of K-Dur 20 since Upsher entered with its generic product in September 2001 leaves no doubt that the exclusion of generic competition forced consumers to pay higher prices for 20 mEq potassium chloride products.

4. Schering's agreement with Upsher had additional anticompetitive effects

Schering's agreement with Upsher not only affected market entry by Upsher, but also served to create an obstacle to entry by other potential generic competitors. *See infra* Sec. I. By securing Upsher's promise to forestall its own entry, the agreement ensured that Upsher would not trigger its exclusivity right. And until that right expired, additional generic entry would be blocked. In this respect, the agreement can be seen as a way of purchasing some insurance

against entry by all generic competition. Even if it was not a perfect barrier to generic entry, it provided Schering with a significant degree of protection.[93]

Although respondents have argued that complaint counsel must demonstrate that respondents specifically intended and conspired to manipulate Upsher's entitlement to 180-day exclusivity, establishing illegality in a civil antitrust action against a horizontal agreement in restraint of trade does not require proof of specific intent to achieve anticompetitive effects.[94] As Professor Areeda has observed, "[w]henever a restraint appears unreasonable in the light of its redeeming virtues and alternatives, the defendant's innocent mental state will not save it . . . . [A] good intention will not save conduct that we are otherwise prepared to judge unreasonably anticompetitive." Phillip Areeda, VII Antitrust Law ¶ 1506 at 390 (1986). Thus, even if respondents did not intend to manipulate Hatch-Waxman's 180-day exclusivity period for anticompetitive purposes, the anticompetitive effect of Schering's agreement with Upsher was to erect an additional barrier to entry by other subsequent generic entrants.

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[93] There might still have been some possibility that another applicant could trigger Upsher's exclusivity by obtaining a favorable court decision in a patent challenge brought by Schering. Schering, however, could avoid this possibility simply by not suing the ANDA filer for patent infringement. Thus, for example, by not suing Andrx, Schering avoided an adverse court decision, and thus left intact Upsher's unexpired 180-day exclusivity period as a barrier to generic entry. *See* CPF 929.

[94] *See United States v. United States Gypsum*, 438 U.S. 422, 446 n. 22 (1978). By contrast, specific intent to achieve certain anticompetitive ends, though not necessarily specific intent to violate the law, is a necessary element of proof regarding certain violations of Section 2 of the Sherman Act.

5. Respondents have failed to offer a plausible procompetitive justification

Paying a potential entrant not to compete is inherently anticompetitive. The record evidence and economic incentives confirm that Schering's payment to its two potential rivals to forgo their patent challenges, in exchange for a specific entry date in the future, would have the effect of delaying entry of a low-cost generic alternative. As a result, consumers were harmed.

This prima facie showing that the agreements are anticompetitive shifts the burden to the respondents to come forward with a plausible procompetitive justification. *NCAA*, 468 U.S. at 113. A justification for anticompetitive conduct is cognizable under the antitrust laws only if it is based on a claim that the restraint enhances competition, for example, by reducing the cost of producing or marketing a product, enabling the competitors to offer a new product, or improving the functioning of the market. Where a justification is based on the opposite premise – that competition is not in the public interest, it is not cognizable and will be disregarded.[95]

The mere assertion of a legitimate goal, moreover, will not serve to establish a plausible justification for anticompetitive conduct. The inquiry into justifications also focuses on whether the restraint actually serves the claimed legitimate objective, and whether the objective can be achieved as well without restraining competition so much.[96] Courts reject proffered justifications

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[95] *See, e.g.*, *NCAA*, 468 U.S. at 116-17; *Professional Eng'rs*, 435 U.S. at 696.

[96] Phillip E. Areeda, VII *Antitrust Law* ¶ 1505 at 384 (1986).

that are pretextual;[97] that are not logically connected to achievement of the purported goal;[98] and that do not achieve or are not necessary to achieve their purported goals.[99]

Respondents fail to put forward a plausible procompetitive justification. They attempt to justify Schering's payments to its potential competitors with economic models that purport to show that agreements with "reverse payments," such as the ones challenged here, could in some circumstances be procompetitive. Each model, however, is flawed. Rather than identifying those situations in which "reverse payments" would in fact result in procompetitive settlements, each theory instead is a road-map to anticompetitive conduct, showing that the parties will always be better off by paying additional compensation for further delayed entry. In addition, none of the justifications were asserted by any of respondents' fact witnesses, who deny reverse payments were made. But respondents want to have it both ways. The fact witnesses deny such payments were made, while the experts explain why the payments were justified. It's time to choose their defense. Finally, in two months of trial, 8600 pages of testimony, and the thousands of admitted exhibits, not one piece of evidence shows that a reverse payment has ever been used to reach a procompetitive settlement — either in this case or in any other.

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[97] *See, e.g., Law v. NCAA*, 134 F.3d 1010, 1024 (10th Cir. 1998).

[98] *California Dental Ass'n*, 526 U.S. at 770-71, *citing Chicago Prof. Sports L.P. v. NBA*, 961 F.2d 667, 674-76 (7th Cir. 1992) (assessing and rejecting logic of proffered procompetitive justifications).

[99] *See, e.g., Chicago Prof. Sports L.P.*, 961 F.2d at 674.

- ***Respondent' theoretical models predict that parties will reach anticompetitive settlements, not procompetitive ones***

Respondents' economic experts offer various theoretical models that purport to show situations in which a reverse payment could end up in a settlement that is not anticompetitive. While these models do lay out limited conditions in which there are settlements that parties prefer to litigation and provide more competition than is expected under litigation, none of these models explain why parties would ever reach those "procompetitive" settlements. In fact, the models themselves predict the contrary. For any procompetitive settlement (as defined by the model), each model shows there are a multitude of anticompetitive settlements that the parties prefer. As a matter of common sense and basic economics, parties will choose the anticompetitive settlements that they prefer more, rather than one of the procompetitive settlements that they prefer less. CPF 1228.

- ***Some of respondents' models actually require anticompetitive assumptions***

In some of respondents' models, the parties actually think they are entering into anticompetitive settlements, but happen to be wrong. CPF 1254-55. These models do not provide justifications for payments from a brand drug maker to its potential generic rival to stay off the market. And respondents fail to explain how allowing parties to enter into agreements they believe are anticompetitive could ever promote competition. While the parties may start with an agreement they only think is anticompetitive, they will always be better off paying more for additional delay. CPF 1244. Thus, if the parties reach any agreement at all, there is every reason to believe (since they already have shown they are not constrained by incentives to act

lawfully) that they will continue to pay for delay until they end up with a settlement that they not only think is anticompetitive, but actually is.

- ***The models rely on the flawed assumption that Schering is risk-averse***

Respondents' assumption that Schering, the patent-holding corporation, is risk-averse contradicts standard economic principles. To maximize profits, corporations should be risk neutral, or close to it, in their decision-making. A multinational corporation, like Schering, with a diversified product portfolio can diversify against risk; the owners of the corporation, the stockholders, can diversify against risk by owning other assets; and corporations can (and do) structure internal incentives to minimize the individual risk preferences of managers. Tr. 34:8067 (Bresnahan). For these reasons, in modeling corporate behavior, economists presume corporations are risk neutral or close to it (Tr. 34:8068-72 (Bresnahan)), and respondents' economic experts provide no legitimate reason to depart from this standard assumption.[100] CPF 1264-77, 1305-17.

- ***Reverse payments have never been used to facilitate a procompetitive settlement***

Most patent cases end in settlement rather than a litigated result. CPF 1419. Yet the record contains no evidence that a payment from a patent holder to an alleged infringer was needed to reach a procompetitive settlement in a patent case. None of the Schering or Upsher

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[100] The literature supports Professor Bresnahan's testimony about corporate decision making. Professor Oliver Williamson in *The Economic Institutions of Capitalism* assumes firms are risk neutral in all of his modeling because risk neutrality "may be a close approximation." Specifically, he bases his assumption on the fact that both firms and stock-holders can diversify against risk. Tr. 34:8068-70 (Bresnahan). In *Modern Industrial Organization* (3d ed.), a standard textbook, Professors Carleton and Perloff state: "The standard assumption in most economic models is that the primary objective of a manager of a firm is to maximize the firm's profits," (Tr. 34:8071), which means that the managers act in a risk neutral manner. Tr. 34:8071-72 (Bresnahan).

businesspeople, or the lawyers called to testify stated that they needed to make such a payment to reach a patent settlement, other than in the agreements underlying this litigation. None of the many experts called by respondents identified a single example of a "reverse payment" being used to facilitate a procompetitive patent settlement. Indeed, a number of respondents' witnesses admitted that they were not aware of any such settlements.[101]

- ***There is no record evidence to support any of respondents' proffered justifications***

Not only are respondents' justifications for the "reverse payment" theoretically flawed, their attempts to justify these payments as procompetitive are wholly inconsistent with their repeated arguments that the $60 million Schering paid to Upsher was for the Niacor-SR license. And there is simply no record evidence to support them:

a. There is no evidence to support Schering's suggestion that Upsher was cash-strapped. Upsher paid the entire $28 million of the first installment to its shareholders; Upsher's financial statements indicated that it had sufficient cash to fund the litigation with Schering and that cash-flow was not a problem. In addition, respondents presented no evidence to suggest, even if Upsher needed cash, why it could not obtain it in any of the ways in which corporations normally do: lines of credit, stock issuance, bond offerings. CPF 1318-25.

b. There is no evidence to support respondents' conclusory assumption that Schering was risk-averse. As a large corporation concerned with maximizing bottom-line profits for its shareholders, Schering would be expected to be risk neutral. Schering's sales of K-Dur were small relative to the total company sales and the sales of Schering's other products were not related to the outcome of the litigation. CPF 1306-08. In short, the evidence confirms the standard economic assumption that, as a large, sophisticated company, Schering sought to maximize its profits during negotiation of the agreements and therefore was not risk averse. Therefore any justification that assumes risk aversion is inapplicable.

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[101] *See* Tr. 24:5912 (Addanki) (not aware of any pharmaceutical patent case settlements (other than those challenged in this proceeding) where there was a naked cash "reverse payment"); Tr. 29:7109 (O'Shaughnessy) (involved in no case in which the patent holder paid the infringer a cash payment up front at the time of the settlement); *see also* CPF 1413-19.

c. There is no evidence that Upsher was concerned about Schering's superior knowledge about the K-Dur 20 market and that such a concern was an obstacle to reaching a settlement without a payment, as would be necessary to support Schering's model that the settlement may have been a signaling device for Schering to provide information to Upsher and/or AHP about the K-Dur 20 market. CPF 1327-30.

d. There is no evidence to support Schering's other model – that concern about third-party entry made it necessary for Schering to pay Upsher and/or AHP in order to settle the patent infringement litigation. Quite to the contrary, the evidence shows that both generic entrants believed they would face third-party competition regardless of when they entered. CPF 1331-37.

- ***Respondents' "guaranteed competition" argument does not justify a payment for delay***

Respondents' claim that the agreements were procompetitive because they permitted generic entry prior to expiration of Schering's patent can be summarily rejected. As complaint counsel's expert explained, from an economic perspective, payment for delay is anticompetitive even if it guarantees future entry. Tr. 34:8085-88 (Bresnahan). And the suggestion that Schering would pay Upsher $60 million and AHP $15 million in order to promote earlier competition to its product is implausible on its face. As the court in the *Terazosin Hydrochloride* case recognized, "the suggestion that Abbott handsomely paid Geneva to spur competition . . . is patently unreasonable." 164 F. Supp. 2d at 1351.

In sum, respondents' justifications do nothing to obviate the obvious anticompetitive character of Schering's payments to its potential generic rivals to stay off the market until a date years in the future. Indeed, all that respondents have shown is that parties will always prefer anticompetitive settlements to procompetitive ones, and that no one can identify a single

settlement in which a payment from the patent holder to the alleged infringer was necessary to facilitate a procompetitive agreement.

C. The Agreements are also *Per Se* Unlawful

The Supreme Court's decision in *Broadcast Music, Inc. v. CBS*, 441 U.S. 1 (1979), teaches that in considering the applicability of the *per se* rule, the inquiry focuses on whether "the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output . . . or instead one designed to 'increase economic efficiency and render markets more, rather than less, competitive.'"[102] As discussed above, the challenged payments to stay off the market directly limit competition on price and output and are inherently likely to delay the entry of lower-priced alternatives and to enable Schering to maintain high prices without fear of losing market share. Each agreement is in economic substance a temporal market allocation arrangement, in which sales of K-Dur 20 are reserved to Schering for several years, while Upsher and AHP are required to refrain from selling their generic versions of K-Dur 20 during that time period. As such, each constitutes a horizontal market allocation agreement, a classic *per se* violation. Respondents have made no plausible argument that Schering's payments to insure that Upsher and AHP stayed off the market for a period of several years were designed to promote competition. They are, therefore, *per se* unlawful.

Respondents contend that the *per se* rule cannot be applied to their challenged agreements because they arose in the context of a settlement of patent litigation, and because they involve

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[102] 441 U.S. at 19-20 (footnotes and citations omitted). *See also Northern Pacific Ry. v. United States*, 356 U.S. 1, 5 (1958) ("[T]here are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable.").

"novel" restraints with which the Commission and the courts lack experience. Neither claim has merit.

The mere fact that the agreements arise in the context of settlement of patent litigation plainly does not make *per se* condemnation inappropriate, as the Supreme Court's decisions in *United States v. Masonite Corp.*, 316 U.S. 265 (1942), and *United States v. Singer Mfg Co.*, 374 U.S. 174 (1963), amply demonstrate. Furthermore, unlike many cases involving antitrust challenges to settlements of patent litigation, this case does not involve owners combining their intellectual property so as to produce a product that otherwise would not exist, or of a patent holder and a new entrant compromising their dispute so as to allow the new entrant to come to market in exchange for compensation to the patent holder. In fact, the challenged agreements are devoid of the kind of efficiencies that can often flow from license agreements that settle conflicting patent claims.[165]

Respondents' claims that this case involves "novel" practices fails because the question in assessing the applicability of the *per se* rule turns on the type of restraint involved, not the industry in which it arises. Along with horizontal price fixing agreements and certain concerted refusals to deal, horizontal market allocation agreements have consistently been held by the Supreme Court to be within the *per se* category. *Palmer*, 498 U.S. 46. Of course, what is

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[165] *See* Federal Trade Commission and United States Department of Justice, *Antitrust Guidelines for the Licensing of Intellectual Property* at § 3.4 (1995):

> To determine whether a particular restraint in a licensing arrangement is given *per se* or rule of reason treatment, the Agencies will assess whether the restraint in question can be expected to contribute to an efficiency-enhancing integration of economic activity. In general, licensing arrangements promote such integration because they facilitate the combination of the licensor's intellectual property with complementary factors of production owned by the licensee.

important is not the mere label "market allocation," but rather the determination in this case that as a matter of economic substance the conduct comports with the standard set forth in *Broadcast Music*, that is, it is a practice that is ""plainly anticompetitive' and very likely without 'redeeming virtue.'" 441 U.S. at 8. In appropriate cases, the Supreme Court has not hesitated to invoke the *per se* rule, even when the restraint is not identical to ones condemned in the past, or occurs in a context that has never before been considered by an antitrust court.[104] Finally, as was discussed above, respondents' suggestion that the courts lack experience with the type of restraint at issue here is particularly inapt. Agreements involving payments from a branded drug maker to an allegedly-infringing generic applicant in return for a promise to stay off the market have already been held to be *per se* illegal in *Cardizem,* 105 F. Supp. 2d 682, and *Terazosin Hydrochloride,* 164 F. Supp. 2d at 1349.

D. Respondents' Arguments that the Challenged Agreements are "Fair" and "Reasonable" Are Not Defenses to the Antitrust Charges

1. Attempting to assess the relative merits of the underlying patent litigation is neither necessary nor appropriate in this case

Respondents have claimed that, even if Schering's $60 million in payments to Upsher and $15 million in payments to AHP were to induce the generic firms' agreement to entry dates several years in the future, the Commission may not find the agreements to be anticompetitive absent some type of determination of the relative merits of the underlying patent cases: either

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[104] *See, e.g., Catalano, Inc., v. Target Sales, Inc.*, 446 U.S. 643 (1980) (summary reversal of a decision that a horizontal agreement on credit terms was not *per se* illegal price fixing); *Arizona v. Maricopa County Med. Ass'n*, 457 U.S. 332 (1982) (rejecting claim that the *per se* rule should not be applied to an agreement among competing physicians on the maximum fees they would accept from insurance companies because the judiciary had little experience applying the price-fixing *per se* rule in the health care industry).

proof that the Upsher and AHP products did not infringe Schering's patent; proof that the alleged infringers likely would have prevailed in the patent case; or proof of the so-called "objective" probabilities of the parties prevailing in the infringement suits (which must then be compared the split in the patent life under the settlement). Respondents simply seek to obscure the fact of the payments. For if Upsher and AHP were merely acceding to the strength of Schering's patent, then why did Schering have to pay them tens of millions of dollars?

Neither patent law nor antitrust law requires the inquiry that respondents urge. Moreover, it is impossible to reliably conduct the inquiry that respondents seek. Finally, Schering's reference to court review of the fairness of class action settlements, in an attempt to assert the relevance of the evidence it offered here concerning the likely outcome of the patent cases, merely illustrates its effort to make this case turn on whether the entry dates that Schering purchased with its unlawful payments were "reasonable" under a standard not grounded in antitrust law.

a. Respondents' contention that a prediction of the likely outcome of the patent cases is necessary has no legal basis

As discussed above, the likely anticompetitive effects of the challenged agreements can be shown without predicting the probabilities of the underlying patent litigations. *See* Section III.B. Patent-holders are entitled to enforce their patents, to refuse to license them to others, and to grant licenses with certain restrictions.[105] But these principles do not mean that a patent holder

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[105] *See, e.g., Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 135 (1969) (citations omitted):

> A patentee has the exclusive right to manufacture, use, and sell his invention. The heart of his legal monopoly is the right to invoke the State's power to prevent others from utilizing his discovery without his consent. The law also recognizes that he may assign to

is entitled to pay a potential competitor not to compete. Moreover, Schering's agreements with Upsher and AHP contain additional restraints that went beyond excluding the allegedly infringing products that were the subject of the patent litigation. They barred entry with *any* generic version of K-Dur 20 – regardless of whether it infringed Schering's patent. CFP 1225-26. In addition, Upsher is prohibited from assisting "any other party challenging the '743 patent" (CX 348 at USL 03187), and AHP is not permitted to conduct or support any bioequivalence studies relating to K-Dur (CX 484 at AHP 05 00056). CPF 881. These restraints plainly fall beyond the scope of any asserted patent rights.

As discussed above, the Supreme Court has condemned anticompetitive agreements between parties with an unresolved patent dispute, notwithstanding the possibility that the patent holder might have been able to secure a court judgment that would have excluded all competition from the allegedly infringing product for the life of the patent.[106] And more recent lower court decisions directly addressing antitrust challenges to settlement agreements arising in a Hatch-Waxman context – the *Cardizem CD*, *Terazosin Hydrochloride*, and *Ciprofloxacin*

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another his patent, in whole or in part, and may license others to practice his invention. But there are established limits which the patentee must not exceed in employing the leverage of his patent to control or limit the operations of the licensee.

[106] *See, e.g., United States v. Masonite*, 316 U.S. 265 (1942) (Supreme Court assumed Masonite's patents were valid and that competing manufacturers had not succeeded in developing non-infringing products (*id.* at 276, 281-82), but condemned agreements wherein competing manufacturers agreed not to compete with Masonite and to adhere to prices set by Masonite).

Hydrochloride cases have uniformly rejected arguments that patent law or antitrust law requires the plaintiff to establish the likely outcome of the underlying patent case.[107]

Respondents cite no authority that a patent holder has the right to pay a potential competitor not to enter the market. Instead, they have relied on a section of a treatise written by Professor Hovenkamp[108] as the legal foundation for their argument that Your Honor should attempt to assess the merits of the underlying patent infringement cases. Their arguments, however, are based on a selective and erroneous reading of Hovenkamp.

Hovenkamp's discussion does not purport to address settlement agreements like the ones at issue here, where the patent-holder pays the alleged infringer as an inducement to refrain from competition. Indeed, at the outset of the section he acknowledges the existence of numerous antitrust cases, such as *Masonite* and *Singer*, condemning arrangements undertaken in settlement of an intellectual property dispute.[109] As noted above, those cases did not involve any determination of the likely outcome of the patent dispute, a fact he expressly notes in his discussion of the *Singer* case that appears earlier in the chapter.[110]

> [A]lthough a declaration of invalidity was a possible outcome of the dispute between Singer and the Swiss firm, it was not the only possible outcome, and *there was no finding by any court or the Patent Office that the patents were in fact invalid*. The crux of the complaint was that by pooling their claims and defending

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[107] *Cardizem*, 105 F. Supp. 2d at 700; *Terazocin Hydrochloride*, 164 F.Supp. 2d at 1352; *Cipro*,166 F. Supp. 2d at 749.

[108] Herbert Hovenkamp, XII *Antitrust Law* ¶ 2046 (1999).

[109] *Id.*, ¶ 2046 at 262 & n. 1.

[110] *Id.*, ¶ 2043 at 240 (noting multiple possible outcomes of the dispute between Singer and its Swiss competitor and the absence of any findings on patent issues).

> validity jointly against the Japanese, rather than vis-a-vis one another, the defendant and his fellow participants violated the Sherman Act.

11 Herbert Hovenkamp, *supra*, ¶ 2043 at 240 (1999) (emphasis added). Another section of the treatise, published in 2001, discusses with apparent approval the decision in *Cardizem* that the agreement involving payments to the alleged infringer in a patent infringement case was *per se* unlawful.[111] Hovenkamp nowhere suggests that the courts in *Cardizem*, *Masonite*, or *Singer* should have attempted to assess the likely outcome of the patent disputes.

The absence of any such suggestion is not surprising. Hovenkamp's analysis requires that the settlement be a "reasonable accommodation" of the parties' dispute, an element not present where a payment to the alleged infringer distorts the defendant's incentives concerning settlement. In sum, there is no authority that supports the claim that an inquiry into the merits of the patent cases is required in this case. On the contrary, the courts have summarily condemned inherently anticompetitive arrangements, even when they were part of a settlement or partial settlement of patent litigation.

b. There is no reliable way to make the determinations that respondents seek

The evidence presented at trial – including the legal opinions offered by Schering's patent law expert, Mr. Miller – confirms that the estimate that respondents propose cannot provide any reliable information that would assist in assessing the agreements' likely competitive effects. As Schering's expert, Mr. O'Shaughnessy, a patent trial lawyer testified at trial, patent litigation is by its very nature unpredictable. Tr. 29:7065. He explained that even the litigants, who are thoroughly steeped in the facts and legal arguments, cannot reliably predict the outcome of patent

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[111] Herbert Hovenkamp, *Antitrust Law* 2001 Supplement at ¶ 1509.

litigation, particularly because they cannot anticipate how the evidence or arguments will be perceived by the fact finder. Tr. 29:7116-17. Consequently, at the time respondents entered into the challenged agreements and withdrew their patent infringement cases from the courts, the outcome in each of the lawsuits was uncertain. And, by virtue of the settlements, we can never know who would have won the patent cases.

Nonetheless, respondents seek a prediction of the likely outcome or a determination of each party's likelihood of success, based on information far more limited than what the parties would have had available to them at the time of the settlement. But any attempt to evaluate the merits of the cases in hindsight is likely to be even less reliable than the parties' internal contemporaneous assessments – information that respondents have steadfastly withheld as privileged. First, we cannot know all of the relevant information. Without the parties' internal documents, we cannot know whether there are facts or theories that were known to the parties but are not revealed in the record of the patent suits. Furthermore, we can never know how the parties would have developed the evidence and legal arguments, what evidence would have been admitted at trial, or how those courts would have weighed the evidence and assessed the legal issues.[112] Moreover, a fundamental condition of the original lawsuits has changed, that is, the adversarial relationship between the patent holder and the alleged infringer. *See* Tr. 15:3279 (Miller). In this proceeding, the alleged infringer no longer has the same incentive to defend its product against the claim of infringement.

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[112] *See* Tr. 15:3290-92 (Miller); •.

Even if it were possible to obtain all the relevant information relating to the litigation, the resulting judgement would represent nothing more than one individual's subjective opinion. As Mr. Miller conceded, there is no recognized methodology for handicapping trials or for testing the reliability of predictions of litigation outcomes. Tr. 15:3296; *see also* Tr. 34:8095-96 (Bresnahan). There is no way to make an "objective" assessment of the probabilities in a statistical sense (such as can be done when tossing a coin or throwing dice) because we cannot do a controlled experiment of the trial. Opinions on the merits of cases that settle before the court decides them can never be tested. Tr. 15:3296 (Miller). Although Schering's economists, Dr. Willig and Dr. Addanki, opined that the competitive effects of the agreements can only be evaluated by comparing the agreed upon-entry dates to some benchmark linked to the merits of the patent cases, neither attempted to analyze the actual agreements under this standard. Tr. 25:5940-42 (Addanki); Tr. 29:7250-60 (Willig).

As unreliable as is the prediction of the ultimate likely outcome of the patent suits, the inquiry that Schering urges would require more. For to compare the split in the patent life under the settlement with the parties' probabilities of prevailing, one would need to be able to quantify those probabilities with a high degree of precision. Tr. 34:8085 (Bresnahan). Each day of delay in generic entry represents harm to consumers. [redacted]; Tr. 6:1241 (Bresnahan). That means even if it was possible to assess the probabilities within a 10% range, we could miss agreements that cost consumers tens, even hundreds of millions of dollars. Such precision is not possible, and Schering has not contended otherwise. Tr. 13:2775 (Nields) ("[W]e don't purport to try to be mathematical about it.").

Furthermore, even if one could accurately estimate and calibrate the probabilities of success in the patent infringement litigation, one would still lack important information that would be needed to assess the economic impact of the settlement. Without knowing the value of competition in later years, knowing the patent probabilities of success reveals nothing about the competitive impact of a settlement. And, thus, multiplying the probability by the remaining years, as respondents advocate, would lead to dramatic errors. Tr. 34:8088-89 (Bresnahan); CPF 1336. For example, if there were ten years left on a patent, and the parties agreed to entry in five years, it would appear that the parties have split the remaining patent life in half. However, if they expected that in six years' time some superior product would come along and replace the entire market, then the settlement maintains the monopoly for 5/6 of the economic life of the patent, and allows competition for only 1/6 of the time. Tr. 34:8090-91 (Bresnahan).

The unreliability of the proposed inquiry into the merits of the patent cases is amply demonstrated by the testimony of Schering's patent law expert, Mr. Miller. While courts have discretion to admit testimony on matters of legal opinion, the opinions offered by Mr. Miller are not helpful because they are speculative, lack foundation, and unreliable. His testimony is based on a very limited universe of information. Mr. Miller did not review the complete record in the infringement cases, had no access to information relevant to the merits that the parties withheld as privileged, and has no basis to predict how the court would have viewed the evidence and arguments of the litigants.[113] Moreover, since respondents have refused to produce any information about their perceptions of the likely outcome of the patent cases, pursuant to claims

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[113] Tr. 15:3288-92 (Miller); •; CPF 1360-63.

of privilege, this information was not available for use on cross-examination to test the basis and validity of Mr. Miller's expert testimony. Finally, Mr. Miller's opinion that the split in the remaining life of the patents under the settlements reflected the merits of the underlying patent suit did not consider whether the economic life of the patent differed from the nominal life of the patent.

Mr. Miller's opinion is merely his personal and subjective view of the limited record he had available to him. [redacted]. In addition, Dr. Banakar concurred with the opinions of AHP's expert in the infringement case, and disagreed with those of Dr. Banker on the infringement issues relating to AHP's product. Tr. 26:6387-92 (Banakar). Indeed, the diverging views of the technical and patent law experts offered by Schering and complaint counsel in this proceeding on legal and technical issues further demonstrate the difficulty in predicting the likely outcome of the underlying patent infringement suits.

Respondents, in advocating a test for competitive harm that cannot be done reliably, urge a rule that would effectively immunize settlements involving payments not to compete. Given the undeniable incentives for branded drug manufacturers and potential generic entrants to reach

patent settlements that involve payments for delayed entry, the threat of serious harm to consumers is too great, and the likelihood of deterring procompetitive agreements is too small, to justify the approach advocated by respondents.

c. Schering's class action analogy is flawed and does not demonstrate the relevance of the evidence it offered regarding the likely outcome of the patent cases

At trial, Schering asserted that evidence as to "whether the outcome of the settlement lines up sensibly with the merits of the [patent infringement] case" is relevant here, because courts reviewing class action settlements consider this question.[114] Of course, the mere fact that courts might make such an inquiry in another context for another purpose does not make it appropriate here. And Schering's apparent effort to draw an analogy to the review of class action settlements does not hold up.

For example, in the class action context there must be a class representative, whose claims must be "typical" of those of the class as a whole, such that the class representative in pursuing its own interests will be advancing the interests of the class.[115] Courts may not substitute a judgment that a settlement is fair for a threshold determination that all of the requirements for class certification criteria have been met.[116] Schering has not explained under

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[114] Tr. 13:2769 (Nields).

[115] Fed. R. Civ. P. 23 (a) states four threshold requirements for all class actions, including a requirement that class representatives will fairly and adequately represent the interests of the class. *Amchem Prod., Inc. v. Windsor*, 521 U.S. 591, 613 (1997).

[116] *Amchem Prod.*, 521 U.S. at 622 ("Federal courts, in any case, lack authority to substitute for Rule 23's certification criteria a standard never adopted – that if a settlement is 'fair,' then certification is proper"). As the Court noted, "the standards [for class certification] set for the protection of absent class members serve to inhibit appraisals of the chancellor's foot kind – class certifications dependent upon the court's gestalt judgment or overarching impression

its analogy which of the parties in the patent infringement litigation it believes should be deemed to represent the interests of consumers that the antitrust laws are designed to protect.[117] In fact, those consumer interests are not aligned with either side, but rather lie in the resolution of patent disputes free from collusive payments that alter the parties' incentives to compete.

Furthermore, proof that a class representative was bribed to settle would doom any class action settlement.[118] Court review of class action settlements is important, given the risk that in settling, the class representative might "sell out" the class. Consequently, courts look to see whether the settlement was negotiated at arms-length and was not collusive in favoring the class representative at the expense of the class. But collusion is precisely what happened here. The generics got a side payment to give up the litigation and stay off the market, and consumers were the losers.

Schering's flawed analogy to class action settlements is like the "consumer advocate" argument it pressed prior to trial. It argues, in effect, that Schering may lawfully compensate a potential competitor in exchange for a promise to refrain from competing, as long as the agreed upon entry date was "reasonable." In so doing, it seeks to persuade Your Honor to abandon

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of the settlement's fairness."). *Id.* at 621.

[117] Private parties are presumed to pursue their own interests. *Town of Hallie v. City of Eau Claire*, 471 U.S. 34, 45 (1985). *See also In re First DataBank Litig.*, 205 F.R.D. 408, 415-16 (D.D.C. 2002) (holding that the FTC could intervene in the case to oppose a counsel fee petition in a class action settlement, and observing "the important difference" between "the personal legal interests that a private litigant may pursue" and the Commission's interest in protecting injured consumers).

[118] Class action settlements face two hurdles: there must be no fraud or collusion in arriving at the settlement; and the settlement must be fair, adequate, and reasonable. *Miller v. Rep. Nat. Life Ins. Co.*, 559 F.2d 426, 428-29 (5th Cir. 1977).

established antitrust principles and to focus on the fairness of the result reached by the challenged conduct, rather than the predictable harm to the competitive process that occurs when an incumbent pays a potential competitor to refrain from entry. Consumers were entitled to a market in which the generic applicants made decisions about whether to settle, and when to enter the market, free from the influence of payments that distort their normal incentives to compete. Schering seeks to have Your Honor substitute some vague fairness standard for the competitive system that the antitrust laws are designed to protect.

2. Schering's claim that its agreement with AHP was approved by the magistrate judge is not a defense

In defending its agreement with AHP as "reasonable" and "fair" to consumers, Schering asserted that the magistrate judge "approved" the settlement terms after an antitrust briefing by Schering's counsel, and that the trial judge "praised" the settlement.[119] There was, of course, no court approval of either the January 1998 settlement terms, or the June 1998 final agreement, which contains additional terms that further reflect the anticompetitive nature of the parties' agreement.[120] Neither agreement was submitted for approval, embodied in any court order, or subjected to any approval process, such as that which occurs in a class action suit. Indeed, there

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[119] *Schering-Plough Corporation's Pretrial Brief* (January 15, 2002) at 13, 21.

[120] *See* discussion at Section II.B., *supra*, and CPF 877-82. The final agreement of the parties included several provisions not contained in the January 1998 agreement in principle: a bar on entry before 2004 with *any* generic version of K-Dur 20; a bar on entry with more than one generic product between 2004 and 2006, regardless of whether the product infringed; a prohibition on AHP conducting or supporting any studies on the bioequivalence of a generic product to K-Dur 20; a prohibition on AHP transferring its ANDA. CFP 881.

is no evidence that the trial judge was even aware of the terms of the January 1998 settlement.[121] Indeed, as Mr. Herman acknowledged, the transcript of the Markman hearing before the trial judge shows the judge expressing a desire to "know none of the details of the settlement" and urging the parties to do only "whatever you think appropriate." Tr. 11:2553. The judge's letter to the parties after their settlement commended them for reaching a compromise resolution of the case, but that letter does not reflect any awareness on his part that Schering had agreed to pay AHP $15 million to secure the agreement on the 2004 entry date.

Schering therefore attempts to concoct an antitrust defense out of the magistrate's involvement in the settlement process. But even if the magistrate urged the parties to agree to the January 1998 terms, the agreement was a purely private contract between the parties, and must be judged in this proceeding according to its likely impact on competition, regardless of what the magistrate may have thought about the settlement.[122]

Schering's emphasis on the "antitrust briefing" it provided the magistrate adds nothing to its argument. There is no evidence that the magistrate saw his role as passing judgment on antitrust issues that might be raised by the settlement. He sought no impartial advice from a

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[121] Although Mr. Nields endeavored to offer Mr. Herman's self-serving claim that the magistrate advised him that the trial judge would be told of the terms of the settlement agreement, in order to show that the trial judge was aware of the terms of the agreement (Tr. 11:2490), Your Honor sustained complaint counsel's hearsay objection. Tr. 11:2490-91 (sustaining hearsay objection after Mr. Nields acknowledged that the testimony was being offered for the truth of the matter asserted).

[122] Schering made no suggestion at trial that the magistrate's involvement in the settlement would provide a Noerr-Pennington defense, and any such claim would fail. The competitive harm here stems from the private agreement between Schering and AHP. The challenged conduct is neither petitioning nor the type of conduct "incidental" to petitioning that the Noerr doctrine protects. *See Andrx Pharm. v. Biovail Corp. Int'l*, 256 F.3d 799, 818-19 (D.C. Cir. 2001).

special master or other independent resource. Instead, he was given an apparently rather limited discussion of antitrust issues, presented by an advocate for Schering. Tr. 11:2589 (Rule) (he was there as Schering's lawyer to represent his client). He may have viewed Schering's protestations as mere posturing, particularly once the terms of Schering's settlement with Upsher-Smith became known. Moreover, according to Mr. Rule's testimony, the magistrate was advised that: (1) a settlement with a payment to stay off the market would raise less serious issues as long as it was based on AHP's lost revenues rather than being calculated as a percentage of Schering's profits; Tr. 11:2584 (told magistrate there was "a big difference" between the two, both in size and conceptually); (2) any settlement that occurred would automatically escape *per se* condemnation. Tr. 11:2581. Both of these propositions – which we submit are incorrect as a matter of law[123] – could well have suggested to the magistrate that no significant antitrust problems would be raised by payments based on AHP's lost revenues. No one ever appeared before the magistrate to oppose the January 1998 agreement or to argue that it would violate the antitrust laws.

Finally, we note that Schering's suggestion that the payment terms – and in particular the $10 million payment contingent on AHP getting an FDA determination that it had an approvable

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[123] Paying a competitor to stay off the market can be expected to harm the competitive process, and thereby injure consumers, regardless of whether the payment is framed in terms of replacing the lost revenues of the generic or paying a portion of the branded company's profits. Indeed, respondents in this proceeding have not argued that a payment based on the potential entrant's lost revenues would be lawful. Second, whether a restraint is properly condemned under the *per se* rule depends on the nature of the restraint. *See* discussion at section III.C., *supra*. We know of no basis to suggest that an otherwise *per se* illegal price-fixing agreement would be judged under the rule of reason if it arose in the context of a court-mediated settlement.

product, what Schering calls "the bet" – came from the magistrate judge[124] is belied by the record. The evidence shows that: (1) AHP proposed tying a payment (AHP asked for $50 million) to FDA approval in a December 1997 letter to Schering counsel (CX 471 at SP 06 00049); and (2) Mr. Driscoll testified that the concept of a declining payment based on the date that AHP's product was deemed approvable was his idea. Tr. 12:2724. The record shows that this term is attributable to Schering and AHP, not the magistrate.

In any event, even if the magistrate had some involvement in the settlement terms, this would not suggest that Schering's agreement with AHP is not anticompetitive. His role was to facilitate a settlement, not to represent consumers or conduct an antitrust review. Any opinion he may have expressed in favor of the settlement is irrelevant to the assessment of competitive effects in this case.

IV. THE AGREEMENTS CONSTITUTE ILLEGAL MONOPOLIZATION AND CONSPIRACIES TO MONOPOLIZE

Because the challenged agreements in this case were capable of perpetuating Schering's monopoly power by delaying the entry of generic K-Dur 20, the agreements constitute both illegal monopoly maintenance by Schering and conspiracies to monopolize between Schering and

[124] *See, e.g.*, Tr. 12:2622-23 (John Hoffman); Tr. 11:2535 (Herman). *See also* Tr. 11:2536-37 (Mr. Nields) ("They may not like the fact that there is direct evidence that Judge Reuter [sic] suggested this term and approved it, but there is direct evidence to that effect and we're presenting through Mr. Herman.").

Upsher, and Schering and AHP, in violation of Section 2 of the Sherman Act[125] and Section 5 of the FTC Act.[126]

The offense of monopolization has two elements: (1) the possession of monopoly power; and (2) the willful acquisition or maintenance of that power through exclusionary conduct. *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966). Thus, when a firm with monopoly power uses its power to exclude or foreclose competition, it violates Section 2, for "[t]he antitrust laws are as much violated by the prevention of competition as by its destruction." *Lorain Journal Co. v. United States*, 342 U.S. 143, 154 n.7 (1951), *quoting United States v. Griffith*, 334 U.S. 100, 107 (1948). Actions taken to preserve monopoly power are "exclusionary" if they involve "conduct, other than competition on the merits or restraints reasonably 'necessary' to competition on the merits, that reasonably appear capable of making a significant contribution to . . . maintaining monopoly power." *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 230 (1st Cir. 1983).

A. Schering Had Monopoly Power in the Market for K-Dur 20[127] at the Time It Entered the Challenged Agreements

Monopoly power, according to the Supreme Court, "is the power to control prices or to exclude competition." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391

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[125] 15 U.S.C. § 2 ("Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States . . . shall be deemed guilty of a felony . . . .").

[126] 15 U.S.C. § 45 (declaring "unfair methods of competition . . . unlawful").

[127] The term "market for K-Dur 20" is used throughout this brief as a shorthand for a market consisting of the manufacture and sale of 20 milliequivalent extended-release potassium chloride tablets and capsules.

(1956) (footnote omitted). This power can be proved in a number of ways. "One type of proof is direct evidence of the injurious exercise of market power. If the plaintiff puts forth evidence of restricted output and supracompetitive prices, that is direct proof of the injury to competition which a competitor with market power may inflict, and thus, of the actual exercise of market power." *Rebel Oil Co. v. Atlantic Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995) (citations omitted).[128] This echoes the Supreme Court's teaching in *FTC v. Indiana Federation of Dentists*, where the Court made clear that proof of actual anticompetitive effects makes market definition and market power inquiries unnecessary:

> Since the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, proof of actual detrimental effects . . . can obviate the need for an inquiry into market power, which is but a surrogate for detrimental effects.[129]

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[128] *See also, United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (per curiam) (monopoly power may be shown through direct evidence of an ability to control prices or indirectly through demonstrating that the firm has a dominant share of a relevant market); *Re/Max Int'l, Inc. v. Realty One, Inc.*, 173 F.3d 995, 1016 (6th Cir. 1999) (same); *Bull Mem'l Hospital, Inc. v. Mutual Hosp. Ins., Inc.*, 784 F.2d 1325, 1336 (7th Cir. 1986) (Easterbrook, J.), *reh'g en banc denied*, 788 F.2d 1223 (7th Cir.1986) ("Market share is just a way of estimating market power, which is the ultimate consideration. When there are better ways to estimate market power, the court should use them.") (citation omitted).

[129] 476 U.S. 447, 460-61 (1986) (citation and internal quotation marks omitted). *See also Flegel v. Christian Hosp.*, 4 F.3d 682, 688 (8th Cir. 1993) (same); *Re/Max*, 173 F.3d at 1019 (applying the *IFD* standard to a monopolization claim under Section 2 of the Sherman Act and observing "we see no reason to believe that monopoly power in the § 1 context is any different from the § 2 monopoly power").

In this case there is abundant direct evidence demonstrating that Schering enjoyed substantial pricing power over K-Dur 20 prior to generic entry; Schering had monopoly power;[130] and its agreements with Upsher and AHP to delay their generic entry was likely to have actual detrimental effects on consumers. Schering's monopoly power is directly proven by evidence that:

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

2. Schering, Upsher, and AHP all forecast that generic K-Dur 20's entry would quickly take a large share of branded K-Dur 20's sales and would significantly lower the average market price paid for K-Dur 20 and its generics;

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

4. When Upsher finally entered the market with generic K-Dur 20 in September 2001, it sold at half the price of branded K-Dur 20 and immediately took a very large percentage of K-Dur 20's sales.

Moreover, the conclusion that Schering had monopoly power over K-Dur 20 is consistent with the large body of empirical research on pharmaceutical competition that shows the significant impact that generics have on their branded counterparts' sales, and on the average price paid for such drugs.

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

Taken together this evidence conclusively establishes that Schering had monopoly power – the power to control prices – in the market for K-Dur 20 at the time it entered into the agreements with Upsher and AHP, and that Upsher's and AHP's agreements with Schering, by delaying generic entry, had significant potential for harming competition and consumers at the time they were entered in 1997 and 1998. This direct evidence of anticompetitive effects obviates the need to engage in the static market definition exercise (with its misplaced reliance on *Brown Shoe Co. v. United States*) that Schering and Upsher have advocated at trial and in their earlier briefs and pleadings.[131]

1. Prior to generic entry, other potassium chloride supplements did not constrain K-Dur 20's pricing

Complaint counsel readily acknowledges that prior to generic K-Dur 20's entry there were a number of pharmaceutical products offered for sale in the United States that could be used to treat potassium deficiency ("hypokalemia"), including generic 8 and 10 mEq potassium chloride products. As the Commission made clear in *Coca-Cola Bottling Company of the Southwest*, however, the relevant inquiry in conducting an antitrust analysis is not whether "certain [products] 'competed' against each in a broad sense," but instead whether such "products were sufficiently substitutable that they could constrain" each other's pricing.[132] A

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[131] Even if one were to conclude that a static analysis of the type respondents argue for is required under Section 2 of the Sherman Act, it is not necessary under Section 5 of the FTC Act. *Cf. FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 239 (1972) (holding that Section 5 empowers the FTC to "define and proscribe an unfair competitive practice, even though the practice does not infringe either the letter of the spirit of the antitrust laws").

[132] *Coca-Cola Bottling Company of the Southwest*, 118 F.T.C. 452, 541 (1994) (rejecting "narrow focus on certain selected pieces of evidence" and reversing the initial decision). *See also* IIA Phillip E. Areeda, Herbert Hovenkamp, and John L. Solow, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* (2d ed. 2002) ¶ 506 at 105 ("[T]he existence of

properly defined antitrust market, as a matter of law, need not include all functionally interchangeable products. Rather, as the Supreme Court has made clear, the functional interchangeability between products provides only "the outer boundaries of a product market." *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). When products, like pharmaceuticals, can be used for the same purpose but differ in terms of price, quality, consumer preferences, or other significant attributes, the products are considered to be differentiated. And, although differentiated products "compete" along some dimensions, as the Third Circuit Court of Appeals recognized in *Smith-Kline Corp. v. Ely Lilly & Co.*, a case involving the pharmaceutical industry, a relevant antitrust market should include only those products that "have the ability – actual or potential – to take significant amounts of business away from each other."[133]

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substitutes does not necessarily preclude 'monopoly' power. It depends on how close the substitutes are in the minds of buyers, on how many buyers consider them to be close, and upon the price-output decisions of those producing the substitutes.").

[133] *SmithKline Corp. v. Ely Lilly & Co.*, 575 F.2d 1056, 1063 (3d Cir. 1978). Likewise, in *Federal Trade Commission v. Staples, Inc.*, the court held that the sale of consumable office supplies through office superstores constituted a relevant market, even though other sellers of office supplies did, to some extent, compete with the superstores: "[T]he mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant product market for antitrust purposes." 970 F. Supp. 1066, 1075 (D.D.C. 1997). Similarly, the Commission and the courts have routinely found that a demonstrated ability to charge significantly different prices for functionally interchangeable products is sufficient to prove that the products are in separate antitrust markets. *See, e.g., Coca-Cola Bottling*, 118 F.T.C. at 542 (1994) (excluding generic carbonated soft drinks and all non-carbonated soft drinks from a brand carbonated soft drink market); *Olin Corp.*, 113 F.T.C. 400, 604 (1990) (excluding liquid pool sanitizers from a dry pool sanitizer market); *United States v. Gillette Co.*, 828 F. Supp. 78, 83-84 (D.D.C. 1993) (separating premium writing instruments from other lower-priced writing instruments). *See also FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 49-50 (D.D.C. 1998) (excluding non-wholesale distributors of prescription drugs from the relevant market of wholesale drug distributors).

Here, there is abundant direct, record evidence demonstrating that branded K-Dur 20 "commanded a substantial price premium over . . . the then existing generics."[134] Indeed, we cannot say it better than Schering's Andrea J. Pickett, product manager for K-Dur 20, did in 1995, when she wrote:

> K-DUR is priced 40-50% higher than a comparable generic dose. However, K-DUR's growth has not been significantly impacted by the prevalence of generics in the Therapeutic Class . . . .[135]

Moreover, despite K-Dur 20's price being as much as 30 percent above generic 8 and 10 mEq potassium chloride products, K-Dur 20's unit sales were growing "substantially faster than other potassium chloride products even though you have to pay more to get one K-Dur 20 than you need to pay to get two of the 10 milliequivalents."[136]

The evidence shows that prior to generic entry Schering priced K-Dur 20 substantially above other potassium chloride products, yet it enjoyed by far the largest sales both in terms of units and dollars. CPF 63, 972-87. Between 1995 and 2000, Schering repeatedly (and profitably) raised the price of K-Dur 20, even while the prices of most other potassium chloride products were stable or falling. CPF 973-75. Despite these price increases, Schering did not lose sales to the other potassium chloride products; instead its share of the total sales of potassium chloride actually increased (CPF 63, 977-87), as did Schering's profits. CPF 64, 976. This

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[134] Tr. 3:475 (Bresnahan). *See also*, CX 18 at SP 23 00039 ("1997 K-Dur Marketing Plan," Sep. 10, 1996, prepared by Schering's marketing manager for K-Dur, Christopher Di Lascia, comparing price of generic 8 and 10 mEq to K-Dur 20 and finding a "30% price advantage" for branded K-Dur 20).

[135] CX 13 at SP 23 003045 ("K-Dur Long Term Strategy," Mar. 8, 1995).

[136] Tr. 3:476 (Bresnahan). *See also*, CX 18 at SP 23 00040 ("K-DUR sales continue to increase, up 20% from the previous year").

evidence demonstrates conclusively that Schering enjoyed substantial pricing power over K-Dur 20 prior to generic entry, and thus that Schering had monopoly power.

Testimony by Upsher executives and the contemporaneous business documents of Schering explain why Schering had monopoly power – the power to control price – over K-Dur 20 prior to generic entry. First, K-Dur's 20 mEq formulation offered superior convenience to the patient, and greater patient compliance to the physician, because of its ease of dosing and microencapsulation. CPF 1037-70.

- According to Denise Dolan, Upsher's marketing manager for Klor Con M20: "[M]y educated assumption was that the market was trending towards the 20 mEq because of ease of dosing and patient compliance."[137]

- Similarly, Phillip Dristas, Upsher's marketing executive, testified: "[T]he 20 mEq has such a large dollar volume and really is such a convenient product for patients * * * [I]f you can swallow it whole rather than taking two tablets, you could take one and some people are absolutely willing to pay more for that convenience."[138]

- In the "1998 K-Dur Marketing Plan," Schering's marketing manager for K-Dur, Christopher Di Lascia, wrote: "K-DUR 20 remains the only once daily, 20 mEq potassium replacement tablet on the market. These features, combined with the versatility in dosing from K-DUR 20's microencapsulation technology have helped our sales and marketing team keep K-DUR 20 without peer in the potassium market."[139]

Second, prior to the introduction of generic K-Dur 20, pharmacies were not allowed to automatically substitute other dosage forms of potassium chloride for K-Dur 20. CPF 34, 26, 1004-09. As Professor Bresnahan explained, this imposed what economists call a "switching

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[137] CX 1493 at 30:4-13 (Dolan dep).

[138] CX 1496 at 40:3-5, 10-13 (Dristas dep).

[139] CX 747 at SP 23 00091 ("1998 K-Dur Marketing Plan," Aug. 1, 1997).

cost" on those seeking to use a non-bioequivalent generic or other potassium chloride product in lieu of K-Dur 20.[140] CPF 35, 1010-15.

The evidence shows that consumers and physicians did not regard other potassium chloride supplements as close substitutes for K-Dur 20, because K-Dur 20 had clear therapeutic advantages over other supplements, as well as a unique dosage strength. It is precisely these factors that permitted Schering to enjoy the significant pricing power that it had over K-Dur 20 prior to generic entry, and it is clear that Schering, and Upsher were each aware of this. CPF 62, 1045, 1047, 1056-60.

2. Schering, Upsher, and • • • forecast the significant impact generic K-Dur 20's entry would have on K-Dur 20's sales

The many market forecasts prepared independently by Schering, Upsher, and • • before the settlements at issue in this case make remarkably similar projections about the significant impact that generic K-Dur 20's entry would have on branded K-Dur 20's sales, and on the market price of K-Dur 20 and its generics. CPF 83-84, 96-97, 816-20, 956-57, 962, 964-67, 970. They show unequivocally that prior to generic entry, Schering was able to make all of its sales of K-Dur 20 at prices far exceeding its costs, and that generic K-Dur 20's entry would have a significant negative impact on K-Dur 20's sales and profits.

- The projections – whether prepared by Schering, Upsher, or • • • – show that generic K-Dur 20 was expected to be priced 50 percent below branded K-Dur 20, and yet the generics would still be sold at a profit.[141]

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[140] Tr. 3:490-91 (Bresnahan).

[141] *See, e.g.*, CX 150 at USL08535 (Notes of Denise Dolan, Upsher's Marketing Manager for Klor Con M20, July 1997, stating "that our [average selling price] would be 50 percent less than K-Dur 20"); •
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- The projections consistently show that generic K-Dur 20 is expected to take from 30 to 50 percent of branded K-Dur's sales within months of entry.[142]

- None of the projections discussing generic K-Dur entry produced by any party in this case show branded K-Dur 20's unit sales and its dollar sales increasing after generic entry. Instead, the "impact of the generic entry was always to decrease those." Tr. 3:462-63 (Bresnahan).

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This evidence confirms that prior to generic entry Schering had the power to control the price of K-Dur 20, and that Schering thus had monopoly power. Additionally, this evidence shows that Schering, Upsher, and • • • • • were each aware of the significant negative impact generic entry would have on K-Dur 20. Lastly, this evidence shows that delaying • • • entry as a third generic also had anticompetitive price effects.

3. Schering planned to introduce a generic K-Dur 20 at substantial discounts to branded K-Dur 20's price

Schering's marketing documents show that it planned to offer its own generic K-Dur 20, through its Warrick subsidiary, at a 50 percent discount off branded K-Dur 20's price.[143] CPF 1115. Schering intended to put this plan into action (and in fact did so) at the time of the first

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• • • • • *See also* Tr. 3:461 (Bresnahan).

[142] *See, e.g.,* •; *see also* CX 18 at SP 23 00044 (Schering "1997 K-Dur Marketing Plan," Sep. 10, 1996, prepared by Schering's Marketing Manager for K-Dur, Christopher Di Lascia, stating that: "Although generic entry is not likely until 1998 the impact of a generic 20 mEq product would be significant, especially for sales subject to mandatary generic substitution laws, Medicaid, and managed care.").

[143] *See, e.g.,* •

independent generic entry. The fact that Schering would offer its own generic K-Dur 20 product at half the brand's price in order to meet generic competition, and that Schering could do so profitably, demonstrates the substantial pricing power Schering enjoyed for K-Dur 20 prior to generic entry.[144] It also demonstrates the benefits to consumers of generic entry -- they can K-Dur 20 from Schering at a generic price – and the harm that results from the delay of generic entry.

4. Since its entry, lower-priced generic K-Dur 20 has taken substantial sales from K-Dur 20

Sales data from the first few months since generic K-Dur 20's entry show that there was a very substantial switch from K-Dur 20, the branded product, to generic K-Dur 20. CPF 988-92. In fact, by November 2001, a mere three months after Upsher finally entered the market, there were "more prescriptions dispensed for the generics than for the brands." Tr. 3:473 (Bresnahan); CPF 989. This evidence shows that "what had been projected came true," and it "shows the monopoly power" Schering enjoyed prior to generic entry. Tr. 3:470, 473 (Bresnahan).

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[144] The reason branded drug companies like Schering launch generics of their own product is because when generic competition is imminent, this practice can increase the branded firm's profits. This is true because it allows the branded company to charge a high price to buyers who value the product the most – those customers who insist on staying with the brand and are willing to pay more for it – while still making profits from sales of the lower-priced generic to the majority of buyers who are no longer willing to pay the full, branded price. In economic terms, this practice is known as "price discrimination"; that is, "selling the identical product to different customers at different prices even though the manufacturer's cost of selling to them is the same." *Brand Name Prescription Drugs Antitrust Litig.*, 186 F.3d 781, 783 (7th Cir. 1999) (Posner, J.). And, as Judge Posner observed in *Brand Name Prescription Drugs*, "[p]rice discrimination implies market power." *Id.* *See also* F. M. Scherer and David Ross, *Industrial Market Structure and Economic Performance* 489 (3d ed. 1990) ("For a seller to practice price discrimination profitably . . . the seller must have some control over price – some monopoly power. A purely competitive firm cannot discriminate profitably."); Hal Varian, "Price Discrimination," *in* 1 *Handbook of Industrial Organization* (1989) (Robert Willig and Richard Schmalensee, eds.) at 599 ("Three conditions are necessary in order for price discrimination to be a viable solution to a firm's pricing problem. First, the firm must have some market power.").

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.[145] CPF 34, 37. Even in these states, however, a physician may insist on use of the brand by writing "Dispense as Written," or "DAW," on the prescription.[146] Many health plans and payers, in turn, encourage or insist on the use of generic drugs rather than their branded equivalent wherever possible, creating an immediate market for the generic equivalents of branded products.[147] CPF 39, 41-49.

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[145] *Compare* Mich. Stat. Ann. § 333.17755(1) (West, WESTLAW through P.A. 2001, No. 280 of the 2001 Regular Sess.) ("the pharmacist may . . . dispense a lower cost but not higher cost generically equivalent drug"), *with*, Conn. Gen. Stat. Ann. § 17b-274 (West, WESTLAW through Jan. 1, 2002) ("A pharmacist shall dispense a generically equivalent drug product for any drug listed in accordance with the Code of Federal Regulations Title 42 Part 447.332 for a drug prescribed for a Medicaid, state-administered general assistance, general assistance, or ConnPACE recipient . . . .").

[146] *See, e.g.*, Mich. Stat. Ann. § 333.17755(3) ("The pharmacist shall not dispense a generically equivalent drug product under subsection (1) if . . . [t]he prescriber . . . writes . . . 'dispense as written' or 'd.a.w.' on the prescription.").

[147] *See generally* Tr. 1:122-23 (Goldberg) (Vice president of clinical pharmacy management for United Healthcare, one of the nation's largest health plans, testifying that "generics really represent one of the most powerful ways that we can help manage pharmacy costs, and so we want to do whatever we possible can to promote the use of generics."); Tr. 2:200 (Teagarden) (Vice president of clinical practices and therapeutics for Merck-Medco Managed Care, the nation's largest pharmacy benefits manager covering 65 million lives, testifying that "[t]he use of generic drugs is of great interest to most of our plan sponsors. They see it as an opportunity to get some cost efficiencies into their plans.").

5. The empirical research on pharmaceutical industry competition supports the conclusion that Schering had monopoly power[148]

The empirical research on pharmaceutical industry competition demonstrates that when a generic drug enters the market it is priced well below its branded counterpart, with the first generic entrant coming in at a price, on average, 25 percent lower than the brand's price.[149] For each generic entrant thereafter, generic prices continue to fall between 5 percent and 7 percent.[150] These same studies have documented the rapid erosion of a branded drug's sales once a generic version is introduced. For example, a Congressional Budget Office study, using a sample of drugs that first faced generic competition between 1991 and 1993, shows that within a year of entry the generic drugs captured roughly 44 percent of the prescriptions dispensed by pharmacies for the respective drug.[151] Similarly, another study using a sample of drugs whose patents expired between 1989 and 1992 found that generics, on average, took 50 percent of the share of prescriptions sold within one year of entry.[152]

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[148] *See, e.g.*, Henry G. Grabowski and John M. Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act," 35 J. L. & Econ. 331 (Oct. 1992); Richard E. Caves, Michael D. Whinston, & Mark A. Hurwitz, "Patent Expiration, Entry and Competition in the U.S. Pharmaceutical Industry," *in Brookings Papers on Economic Activity: Microeconomics* 1 (1991); Roy Levy, Federal Trade Commission, "The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change," Bureau of Economics Staff Report (1999).

[149] Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards* (1993).

[150] Richard G. Frank & David S. Salkever, "Generic Entry and the Pricing of Pharmaceuticals," 6 J. Econ. & Mgmt. Strategy 75 (Spring 1997).

[151] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (1998).

[152] Grabowski and Vernon, *supra* at n. 148.

The empirical research supports the conclusion that delaying generic entry has anticompetitive effects. When generic products are able to enter the market, a substantial segment of consumers avail themselves of the lower-priced generic products, thereby realizing significant cost-savings of 25 percent or more relative to the pre-entry period. If, however, generic entry is delayed, consumers lose the opportunity to reap the substantial benefits of lower-priced generics.

6. K-Dur 20 is the appropriate market in which to assess the anticompetitive effects of the agreements

The evidence discussed above shows that K-Dur 20 and its generic equivalents is the appropriate market in which to assess the anticompetitive effects of the respondents' agreements. As set forth in detail above, only generic K-Dur 20 had the potential to take significant amounts of business away from Schering's K-Dur 20. No other potassium chloride product could have the effect on K-Dur 20's sales and profitability that entry of a generic version of K-Dur 20 was expected to have and, in fact, did have. Accordingly, the relevant market in which to analyze the anticompetitive effects of Schering's agreements with Upsher and AHP is the sale of K-Dur 20 and its generic equivalents in the United States.

This market accurately reflects the unique competitive dynamic that typically exists between a branded drug and its generic counterpart.[153] Indeed, it is precisely this unique

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[153] Schering's counsel, Mr. Nields, has readily acknowledged the unique nature of competition between a branded drug and its generic equivalent, as revealed by the following sequence of questions Mr. Nields asked during his cross-examination of Professor Bresnahan:

> Q: Now, Professor, isn't it true that the competition that exists between a brand name company and it's A-B rated generic has some very special features to it?
>
> A: Yes. I mean, the – you mean, the competition between the brand name

competition - the fact that generic entry effectively commoditizes its branded equivalent overnight – that explains why Schering was willing to pay Upsher and AHP a combined $75 million to delay generic entry.

Schering and Upsher, however, insist the relevant market consists of all potassium chloride supplements, and that K-Dur 20's share of that market is too small to infer monopoly power.[154] To accept respondents' definition of the relevant market, one would have to conclude that the entry of generic K-Dur 20 makes little difference to competition and to consumers. Indeed, to accept respondents' definition of the relevant market one would have to conclude that Schering was acting irrationally when it spent millions of dollars bringing its patent lawsuits against Upsher and AHP, and that Upsher and AHP were acting irrationally when they made their investments to enter the market for K–Dur 20, including the costs of defending against Schering's lawsuits.

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firm's product and the A-B rated generic to the product.

Q: Yes, I should have asked the question that way.

A: Yes.

. . .

Q: And isn't it true that the generic virtually always, if not always, underprices the brand name?

A: That's true, too.

. . .

Q: And they always take sales away form the brand name, correct?

A: Yes.

Q: And indeed, by law they would almost have to.

A: I think that's right.

Tr. 6:1176-80 (Bresnahan).

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

Record evidence belies respondents' contentions. There is no doubt that patients who take generic K-Dur 20, and those who pay the bills for prescription drugs, realized significant economic benefits when generic K-Dur 20 finally became available. There is no doubt that Schering, Upsher, and AHP were aware of this when they entered their illegal agreements. And, there is no doubt that by delaying the entry of generic K-Dur 20 under the terms of the agreement, Schering, Upsher, and AHP harmed competition and consumers.

B. Schering Willfully Maintained Its Monopoly in the Market for K-Dur 20 through Exclusionary Conduct

The second part of the monopolization test set forth by the Supreme Court in *Grinnell Corp.* – that is, the willful maintenance of monopoly through exclusionary conduct – is established by the same evidence, discussed in Section III above, demonstrating that the agreements between Schering and Upsher and between Schering and AHP unreasonably restrained competition.[155]

As the Court of Appeals for the D.C. Circuit held in *United States v. Microsoft Corp.*, a plaintiff in a monopolization case need not present direct proof that the defendant's continued monopoly power is precisely attributable to its anticompetitive conduct. 253 F.3d 34, 79 (D.C. Cir. 2001) (per curiam). Rejecting Microsoft's argument that the government did not establish a causal link between Microsoft's foreclosure of Netscape's and Java's distribution channels and the maintenance of Microsoft's operating system monopoly, the court held that – in an action for injunctive relief – the court could infer causation when "a defendant has engaged in

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[155] *See generally* Ernest Gellhorn and William E. Kovacic, *Antitrust Law and Economics* (4th ed. 1994) at 122 (citing various Supreme Court cases in support of the proposition that Section 2 of the Sherman Act condemns "the abuse of monopoly power as evidenced by trade practices which would violate Section 1 if adopted by two parties acting jointly").

anticompetitive conduct that 'reasonably appear[s] capable of making a significant contribution to . . . maintaining monopoly power.'" *Id.* at 79, *quoting* Areeda & Hovenkamp, III *Antitrust Law* ¶ 651c at 78 (1996). The court specifically held that this inference of causation applied even when the exclusionary conduct is aimed at nascent competitive technologies. "Admittedly, in the former case there is added uncertainty, inasmuch as nascent threats are merely *potential* substitutes. But the underlying proof problem is the same -- neither plaintiffs nor the court can confidently reconstruct a product's hypothetical technological development in a world absent the defendant's exclusionary conduct." *Id.* (emphasis in original). It was not the government's burden to establish a " but for" world -- to show that Java or Netscape would have developed into viable substitutes for Microsoft's operating system. Rather, the central question was whether "as a general matter the exclusion of nascent threats is the type of conduct that is reasonably capable of contributing significantly to a defendant's continued monopoly power" and whether the potential entrants constituted nascent threats at the time the conduct was undertaken. *Id.* As the court recognized, " it would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will . . . ." *Id.*

The evidence shows that prior to entering the agreements with Upsher and AHP, Schering was the only company making a 20 mEq potassium chloride tablet or capsule. When Upsher and AHP tried to invent around Schering's '743 patent covering K-Dur 20 and were seeking to enter the market with their own generic versions of K-Dur 20, Schering sued them for patent infringement. Because there were doubts at to whether the patent suit would keep Upsher and AHP out of the market, Schering paid them to delay their marketing of a 20 mEq potassium chloride tablet, thereby excluding competition, and maintaining Schering's K-Dur 20 monopoly.

This evidence shows that the agreements, in the language of *Microsoft*, "reasonably appear capable" of preserving Schering's monopoly power in the market for K-Dur 20, keeping K-Dur 20's sales at the monopoly price, for the benefit of Schering, Upsher, and AHP.

C. Schering's Monopolizing Conduct Had No Legitimate Business Justification

As discussed in Section III B 5 above, the agreements between Schering and Upsher and between Schering and AHP to delay generic entry and monopolize the market for K-Dur 20 lacked any legitimate business justification. They were "not motivated by efficiency concerns,"[156] did not relate "directly or indirectly to the enhancement of consumer welfare,"[157] and were not the "consequence of a superior product, business acumen, or historic accident."[158]

D. Schering, Upsher, and AHP Entered into Conspiracies to Monopolize the Market for K-Dur 20

The evidence also conclusively proves that Schering and Upsher, and Schering and AHP, conspired to monopolize the market for K-Dur 20. The elements of a conspiracy to monopolize consist of: (1) the existence of a combination or conspiracy; (2) an overt act in furtherance of the conspiracy; and (3) specific intent to monopolize.[159]

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[156] *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 610 (1985).

[157] *Data Gen. Corp., v. Grumman Sys. Support Corp.*, 36 F.3d 1147, 1183 (1st Cir. 1994).

[158] *Grinnell Corp.*, 384 U.S. at 570-71.

[159] *See, e.g., Volvo N. Am. Corp. v. Men's Int'l Prof'l Tennis Council*, 857 F.2d 55, 74 (2d Cir. 1988). Courts have generally held that no proof of market power or market definition is needed to find a violation of conspiracy to monopolize. *See, e.g.*, IIIA Phillip E. Areeda and Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* (2d ed. 2002) ¶ 809 at 390 n.2 (collecting cases).

Like the principles governing conspiracies in restraint of trade under Section 1 of the Sherman Act, the first element of a conspiracy to monopolize, proof of agreement, is satisfied by the written settlement agreements that Schering entered into with Upsher and AHP. CPF 170-75, 846-51. The second element, an overt act in furtherance of the conspiracy, is met by Schering's payment of $60 million to Upsher and $15 million to AHP, the acceptance of those payments by Upsher and AHP, the voluntary dismissal of the patent litigations, and the delayed launch of Upsher's product and no launch of AHP's generic product. CPF 111, 165, 250-57, 831, 883-86.

The third element, a specific intent to monopolize, may be shown either by direct evidence of the respondents' state of mind, or by inference from the respondents' conduct.[160] Numerous cases reflect the fact that courts properly refuse to infer the requisite specific intent where the alleged conspiracy does not make economic sense; for example, a conspiracy between a purchaser and its supplier.[161] Ordinarily it would be irrational for a buyer to seek to help its supplier to obtain the ability to charge monopoly prices for the supplied product. Where, however, the parties have engaged in a horizontal conspiracy in violation of Section 1 of the Sherman Act, the evidence demonstrates a shared incentive to maintain a monopoly and to split monopoly profits, and the evidence shows the parties' awareness that their conduct threatens to

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[160] *See American Tobacco Co. v. United States*, 328 U.S. 781, 809-10 (1946).

[161] For example, in a case relied on by Upsher, *Microsoft Corp. Antitrust Litigation*, 127 F. Supp. 2d 728 (D. Md. 2001), the alleged conspiracy was that computer manufacturers had conspired with Microsoft to maintain Microsoft's monopoly in the operating software market and the word processing and spreadsheet markets. The court held the complaint failed to state a claim for conspiracy to monopolize, pointing to the defendants' explanation that the conspiracy alleged was "inherently implausible" because "it would be irrational . . . for them, as purchasers, to seek to maintain monopolies that Microsoft, their supplier, possessed." There were no facts alleged, the court held, from which it reasonably could be inferred that the manufacturers believed that preservation of Microsoft's monopolies was in their own interest. *Id.* at 731-32.

create or maintain that monopoly[162] – this is powerful evidence from which to infer their specific intent.

Schering's statements and actions demonstrate its specific intent to maintain its monopoly of the K-Dur market, while Upsher's and AHP's statements and actions reveal their intent to share with Schering the returns from doing so. Schering's state of mind and conduct, from which one may infer its specific intent to participate in a conspiracy to monopolize, includes:

- Schering knew the impact that a generic K-Dur 20 would have on branded K-Dur 20's sales. CPF 83-84.

- Schering entered into agreements with Upsher and AHP to delay the entry of their generic K-Dur 20 products. CPF 170-75, 846-49.

- Schering knew it had to compensate Upsher for staying off the market and it did so. CPF 199, 219-24. The June 1997 memorandum from a Schering vice president to the Schering Board of Directors recommending approval of the Upsher agreement states that Upsher was seeking "an income stream to replace the income Upsher-Smith anticipated earning if it were able to successfully defend against Key's infringement claims." CX 338 at SP 12 00268. In fact providing Upsher with such an income stream was a "prerequisite" of a settlement agreement. CX 338 at SP 12 00270; CPF 219.

- Another Schering document shows that Schering calculated how much it would need to compensate Upsher for agreeing to delay its generic entry. • • • • • • • •
• •

- Schering paid Upsher $60 million to delay entry of its generic K-Dur 20 product. CPF 179-85.

- Schering paid AHP $15 million to delay entry of its generic K-Dur 20 product. CPF 883-85.

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[162] *See Instructional Sys. Dev. Corp. v. Aetna Casualty and Surety Co.*, 817 F.2d 639, 647 (10th Cir. 1987) (evidence of specific intent shown where a co-conspirator was aware of the other's monopolistic desires and parties' joint conduct furthered those desires).

Upsher's state of mind and conduct, from which one may infer its specific intent to participate in a conspiracy to monopolize, includes:

- Upsher knew the impact that entry of its generic K-Dur 20 would have on Schering's K-Dur 20 sales. CPF 96-97.

- Upsher entered into an agreements with Schering to delay the entry of its generic K-Dur 20 product. CPF 166-69.

- Upsher asked for compensation from Schering for agreeing to stay off the market until 2001. Upsher sought payment to replace the revenue it lost by delaying entry of its generic product, and Mr. Troup, on behalf of Upsher, justified this demand with reference to the profits Schering would lose if Uphser were to enter the market.[163] CPF 168.

- During the negotiations, Upsher presented an analysis of Schering's potential financial losses as a result of Upsher's entry into the market for K-Dur 20. Tr. 15:3559 (John Hoffman). CPF 167.

- Upsher accepted the payment of $60 million from Schering, and it refrained from entering the market with its generic product until 2001. CPF 171, 174.

AHP's state of mind and conduct, from which one may infer its specific intent to participate in a conspiracy to monopolize, is set forth in Section XX.C. of the Complaint Counsel's Proposed Findings of Fact.

V. JURISDICTION AND INTERSTATE COMMERCE

Section 5 of the FTC Act, 15 U.S. C. § 45, directs the Commission to prevent "persons, partnerships, or corporations" from using unfair methods of competition "in or affecting commerce." Schering and Upsher are corporations.[164] Their challenged activities to delay the

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[163] Tr. 23:5413-14 (Troup); Tr. 15:3543 (John Hoffman); Tr. 15:3557(John Hoffman) (Upsher wanted a payment in return for not entering the K-Dur market); CX 1529 at 111-12 (Troup IH); CX 1509 at 32-33 (John Hoffman dep); CX 1511 at 19-20 (Kapur dep).

[164] Section 4 of the FTC Act defines a corporation to include any company that is "organized to carry on business for its own profit or that of its members ." 15 U.S.C. § 44.

sale of generic K-Dur-20 have an obvious nexus to interstate commerce, and neither Schering nor Upsher has contended otherwise (notwithstanding Upsher's refusal to stipulate that it engages in interstate commerce).[165]

The Commission's interstate commerce jurisdiction is as broad as that conferred under the Sherman Act.[166] To demonstrate the requisite effect on interstate commerce, it is sufficient to show that, "as a matter of practical economics," the challenged agreement "could be expected to" affect the flow of interstate commerce.[167] There is no need to prove an actual effect on interstate commerce[168] or to quantify the expected effect.[169]

There can be no serious question that a conspiracy to forestall the introduction of generic competition to Schering's widely-prescribed K-Dur 20 is covered by federal antitrust law. Both

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Schering has admitted it is a corporation within the meaning of the FTC Act. Schering Answer ¶ 7. Upsher is organized to carry on business for its own profit. Upsher-Smith's Objections and Responses to Complaint Counsel's First Set of Requests for Admissions, Answers to Requests Nos. 1, 2. *See also* CX 1 (Upsher Articles of Incorporation).

[165] Upsher-Smith Answer ¶ 4.

[166] *American Medical Association*, 94 F.T.C. 701, 994 (1979), *aff'd*, 638 F.2d 443 (2d Cir. 1980), *aff'd by an equally divided Court*, 455 U.S. 676 (1982). The Supreme Court has repeatedly emphasized the breadth of federal antitrust jurisdiction, even in cases challenging wholly intrastate conduct of local actors. *See, e.g., Summit Health, Ltd. v. Pinhas*, 500 U.S. 322 (1991); *McLain v. Real Estate Board of New Orleans, Inc.*, 444 U.S. 232 (1980); *Hospital Building Co. v. Trustees of Rex Hospital*, 425 U.S. 738 (1976); *Goldfarb v. Virginia State Bar*, 421 U.S. 773 (1973). *See also Hammes v. AAMCO Transmissions, Inc.*, 33 F.3d 774, 778-81 (7th Cir. 1994) (Posner, J.) (discussing breadth of federal antitrust jurisdiction).

[167] *Rex Hospital*, 425 U.S. at 745.

[168] *Pinhas*, 500 U.S. at 330 (because essence of violation is the illegal agreement itself, "proper analysis focuses, not upon actual consequences, but rather upon the potential harm that would ensue if the conspiracy were successful").

[169] *Goldfarb*, 421 U.S. at 785.

respondents are engaged in the interstate sale of pharmaceutical products. Schering has stipulated as to its own business activities,[170] and the record also demonstrates Schering engaged in interstate activity with respect to K-Dur 20 in particular.[171] Upsher's involvement in interstate commerce is amply shown by record evidence, which shows: Upsher sells all of its products, including the Klor-Con line, to customers and wholesalers across state lines;[172] has sales representatives located both in and outside of its home state of Minnesota;[173] and receives raw materials necessary for the manufacture of Klor-Con M20 from companies outside of Minnesota.[174] The challenged agreements to forestall entry by Upsher and AHP – which precluded sales by the generic applicants for several years and enabled Schering to maintain its level of sales – necessarily would have a substantial effect on such interstate commerce. Moreover, by virtue of the effect of the challenged agreements on the triggering of the 180-day exclusivity provision of the Hatch-Waxman Act, the impact of respondents' activities extends to other market participants as well.[175]

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[170] Schering's Answer ¶¶ 7, 8.

[171] For example, Schering targeted its marketing and sales efforts for K-Dur 20 at consumers throughout the United States. CX 18 at SP 23 00044.

[172] Tr. 20:4874-75 (Dritsas). At least 70 percent of Klor Con M20 that was being shipped for sale, was shipped to locations outside of Minnesota, Upsher's home state. Tr. 21: 5076-77 (Kralovec).

[173] Tr. 21:4997-99 (Freese).

[174]Upsher-Smith's Objections and Responses to Complaint Counsel's First Set of Requests for Admissions, Answers to Requests Nos. 16, 17.

[175] The Supreme Court has made it clear that the inquiry concerning interstate commerce includes consideration of the impact of the restraint on "other participants and potential participants in the market." *Pinhas*, 500 U.S. at 332.

VI. REMEDY

It is well established that "the Commission has wide discretion in its choice of remedy deemed adequate to cope with unlawful practices."[176] Having found a violation, "the Commission is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past. . . . it must be allowed effectively to close all roads to the prohibited goal, so that its order may not be bypassed with impunity."[177] Thus, the courts recognize the Commission's authority to enjoin "like and related" practices beyond the specific unlawful practices challenged in the complaint,[178] for, as the Supreme Court has expressed it, respondents found to have violated the law "must expect some fencing in."[179] As long as the remedial provisions bear "a reasonable relationship to the unlawful practices found to exist," they are proper.[180]

The proposed order, which appears at Appendix A of this brief, is designed to remedy respondents' violations of the law and to prevent them from engaging in similar unlawful agreements in the future. We first address the need for the order and then explain its provisions.

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[176] *Jacob Seigel Co. v. FTC*, 327 U.S. 608, 611 (1946). *See also FTC v. National Lead*, 352 U.S. 419, 428-29 (1957); *FTC v. Cement Institute*, 333 U.S. 683, 726 (1948); *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 392 (1965).

[177] *FTC v. Ruberoid*, 343 U.S. 470, 473 (1952). *Cf. National Soc'y of Prof'l Eng'r v. United States v.*, 435 U.S. 679, 698 (1978) (in fashioning remedy for an antitrust violation, it is "entirely appropriate" to go "beyond a simple prescription against the precise conduct previously pursued").

[178] *FTC v. Mandel Bros., Inc.*, 359 U.S. 385, 393 (1959); *see, e.g., Amrep Corp. v. FTC*, 768 F.2d 1171 (10th Cir. 1985).

[179] *FTC v. National Lead Co.*, 352 U.S. at 431.

[180] *Jacob Seigel Co. v. FTC*, 327 U.S. at 613.

A. An Order Is Needed to Prevent Further Unlawful Conduct

To demonstrate the need for prospective relief, complaint counsel need only show a "cognizable danger" of a repeated violation.[181] The question is not whether a respondent will engage in precisely the same conduct, but whether there is a danger that it will engage in future violations of the same type.[182] Questions about the need for an order arise most often when a respondent claims to have abandoned the challenged conduct (though abandonment by itself will rarely be sufficient to eliminate the need for relief),[183] or where there are changes in market conditions that make future violations unlikely.[184]

In this case there is clearly a cognizable danger of a repeated violation. Respondents entered into and carried out an unlawful agreement to delay generic competition (in Schering's case, two agreements). The agreements were never abandoned or disavowed and, in fact, remain in force. Furthermore, there have been no changes in market conditions that would eliminate their ability – or the powerful incentives – to enter into similar agreements, or that would otherwise make a repeated violation unlikely. Both respondents remain in the pharmaceutical

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[181] *United States v. W.T. Grant*, 345 U.S. 629, 633 (1953); *SCM Corp. v. FTC*, 565 F.2d 807, 812-13 (2d. Cir. 1977) ("[T]he violation is itself the best evidence of the possibility of future such occurrences").

[182] *See TRW, Inc. v. FTC*, 647 F.2d 942, 953 (9th Cir. 1981).

[183] *See, e.g., American Medical Ass'n v. FTC*, 638 F.2d 443, 451 (2d Cir. 1980), *aff'd by an equally divided court*, 455 U.S. 676 (1982) (rejecting claim of abandonment).

[184] *Borg-Warner Corp. v. FTC*, 746 F.2d 108, 110 (2d. Cir. 1984) (respondent sold auto parts division, eliminating interlocking directorate); *International Harvester*, 104 F.T.C. 949, 1070 (1984) (change in tractor technology made recurrence of violation unlikely).

industry.[185] • , and Schering is currently engaged in several patent infringement suits to protect some of its branded products against competition from potential generic entrants. CPF 1479. To be sure, the mere existence of a past violation does not by itself justify prospective relief without regard to other circumstances. But here there are no other circumstances that would suggest that respondents' past illegal conduct does not create a risk of further unlawful conduct.[186]

Although respondents have asserted that the case is moot[187] and that an order is unwarranted here,[188] they have not even purported to claim that there is no risk that they will enter into similar agreements in the future. Instead, they have either (a) observed that certain remedial provisions (such as requiring Schering to grant an immediate license to Upsher) are no longer needed or (b) stated that there is no risk that they will enter into the same agreement

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[185] When a respondent does withdraw from the business in which the challenged practices occurred, an order may be unnecessary if there is no likelihood of it re-entering the industry, and the order is limited to practices within that industry. *See National Lead Co. v. FTC*, 227 F.2d 825, 839-840 (7th Cir. 1955) (vacating order as to one respondent), *rev'd on other grounds*, 352 U.S. 419 (1956); *Ethyl Corp.*, 101 F.T.C. 425, 461-62 (1983) (vacating order as to one respondent), *rev'd on other grounds*, 729 F.2d 128 (2d Cir. 1984).

[186] *See, e.g., TRW*, 647 F.2d at 954 (no danger of recurrent violation where TRW terminated the offensive interlocking directorate before issuance of the complaint "and arguably before notice of the FTC's investigation"; violation was not a blatant one; and it had implemented a compliance program whose effectiveness was not in question).

[187] *See Respondent Schering-Plough Corporation's Statement of the Case Involving Schering and Upsher-Smith* (September 18, 2001) at 9-10; *Respondent Schering-Plough Corporation's Statement of the Case Involving Schering and ESI-Lederle* (September 18, 2001) at 8.

[188] *See Upsher-Smith's Memorandum of Law in Support of its Motion to Dismiss Due to Complaint Counsel's Failure to Establish a Prima Facie Case* (February 12, 2002) at 46.

regarding K-Dur 20. These arguments do not undermine the need for an effective ban against future unlawful agreements, let alone make the case moot.[189] The former argument merely means that the order need not address certain particular restraints that were in place at the time the complaint was filed but have now expired. As to the latter argument, as was noted above, the issue with respect to recurrence is with "repeated violations" and not merely repetition of precisely the same conduct.[190] In short, nothing offered by respondents casts doubt on the conclusion that an order is needed to protect consumers against the cognizable danger of a recurrent violation.

B. The Proposed Order

The proposed order is designed to prevent respondents from entering into certain agreements that are likely to unreasonably limit competition from new generic drug products. For a period of ten years, the order would: (1) generally prohibit agreements in which a brand name drug company (the NDA holder) makes a payment, whatever the form, to a potential generic competitor (an ANDA filer), and the ANDA filer agrees not to market its product for some period of time (Parts II and V); and (2) bar agreements between the NDA holder and an ANDA filer in which the generic competitor agrees not to enter the market with a non-infringing

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[189] To say the case is moot means it must be dismissed without an adjudication of legality. While complaint counsel bear the burden to show the need for injunctive relief, respondents bear the "heavy burden" to show that there is "no reasonable expectation that the wrong will be repeated." *United States v. W.T. Grant Co.*, 345 U.S. at 633 (1953) (rejecting mootness defense). *See also United States v. Concentrated Phosphate Assn, Inc.*, 393 U.S. 199, 203 (defendant claiming mootness bears burden to show that it is "absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur").

[190] *See TRW*, 647 F.2d at 953-54 (explaining that "recurrent violation" issue, used in assessing mootness and need for relief, concerns "repeated violations of the same law, and not merely with repetition of the same offensive conduct").

generic product (Part III), or agrees not to relinquish Hatch-Waxman exclusivity rights (Part IV). In addition, the order has been crafted with certain exceptions that allow conduct that is unlikely to be anticompetitive.

Part II of the proposed order would generally prohibit each respondent from entering into an agreement resolving a patent infringement claim against an ANDA product in which the ANDA filer receives anything of value and agrees not to market its product for some period of time, subject to an exception. The order prohibits not merely cash payments to induce delayed entry, as occurred in this case, but also other agreements in which the NDA holder provides something of value to the potential generic entrant, and the ANDA filer agrees in some fashion not to sell its product. Absent such an approach, a company could evade a prohibition on cash payment by substituting other things of value.

The proviso to the general ban in Part II addresses agreements in which the value received by the ANDA filer does not go beyond: (1) the right to market the ANDA product prior to expiration of the allegedly infringed patent; and (2) an amount equal to the patent-holder's expected future litigation costs, up to a maximum of $2 million. For agreements that provide such value to the ANDA filer, the order requires that the respondent notify the Commission at least 30 days prior to consummating the agreement, and prescribes a "second request" process akin to that used under the Hart-Scott-Rodino Act for mergers, to enable the Commission to seek more information in cases where the agreement appears to raise competitive concerns. The proviso reflects the fact that an agreement that only involves an agreement to split the remaining patent life may often be expected to result in an entry date that reflects the parties' expected entry date if the case were litigated. The order allows a payment based on the NDA-holder's expected

future litigation costs because the NDA-holder would have to expend that amount to achieve its expected result from litigating. Thus, an agreement involving a payment in that amount would not be expected to have the purpose and effect of purchasing a later entry date than would be expected if the litigation were pursued. A cap on the payment for expected future litigation costs is necessary to ensure that this provision does not permit payments, made as compensation for a future entry date, to be characterized as forecasted litigation costs.

The notice provision contained in the proviso to Part II for certain agreements not prohibited by Part II, is necessary because an agreement in which an ANDA filer agrees to a future entry date can raise risks of competitive harm by virtue of the exclusivity provisions of the Hatch-Waxman Act. The required notice will enable the Commission to assess the impact of the agreement in light of the regulatory framework for triggering exclusivity rights. In addition, the notice provision may serve to deter anticompetitive agreements.

The ban under Part II of the order would prohibit patent settlements with ANDA filers that contain so-called "side deals," without regard to whether those side deals were based on fair market value. While this provision may prohibit some agreements that would not be unlawful, it is both reasonable and necessary in order to provide an effective remedy, and it is fully justified given the record in this case. First, as the record evidence demonstrates, NDA-holders and ANDA filers have powerful incentives to enter into agreements involving payments for delayed entry (CPF 1150-58), making it likely that even where the ANDA filer transfers a valuable license or other asset, the NDA holder can be expected to pay more than market value for that asset. Second, determining in any given case whether a payment is for a license or other asset, rather than for the agreement to the entry date, can be an involved, fact-intensive process, as the

adjudication in this case illustrates. An order provision that turned on whether the side deal was for fair market value would make enforcement of the order unduly complicated and create a substantial loophole. In light of respondents' past violations, this "fencing-in" is reasonable and necessary to provide effective protection to consumers.

The remaining prohibitions of the order are similar to those contained in consent orders issued by the Commission in *Abbott Laboratories,* C-3945 (May 22, 2000); *Geneva Pharmaceuticals*, C-3946 (May 22, 2000); *Hoechst Marion Roussel, et al.*, D.9293 (May 8, 2001); and *American Home Products*, D. 9297 (April 2, 2002). Part III of the proposed order bars agreements not to enter with a non-infringing product. This provision directly addresses conduct challenged in the Commission's Complaint. Part IV of the proposed order bars agreements in which a first ANDA filer agrees not to relinquish its right to the Hatch-Waxman 180-day exclusivity period. Although the challenged agreements in this case did not include such a restraint, such provisions have been used in other agreements to delay generic entry, and the ban is reasonably related to the unlawful practices challenged in this case. The order does not bar such agreements when they arise in the context of licensing arrangements where: (1) the ANDA first filer comes to market immediately with a generic product; (2) the 180-day exclusivity period has been triggered or relinquished; and (3) the respondent provides the prescribed notice to the Commission. Since concerns about such provisions arise because of their likely blocking effect on third parties, the order would not prohibit such agreement where no such blocking effect would occur.

Part V bars agreements that involve payment to an ANDA filer where the ANDA filer agrees not to enter the market for a period of time and the patent infringement litigation

continues (so-called "interim settlement agreements"). Although the challenged conduct here was an agreement in connection with a final settlement of litigation, rather than an interim agreement, this provision is appropriate in light of the significant antitrust concerns raised by interim agreements and the need to prevent recurrence of violations similar to those challenged in the complaint. As with Part II, it is necessary to cover not only cash payments but also the NDA holder's providing "anything of value" to the ANDA filer, in order to prevent evasion of the order. On the other hand, while the harm from the kind of payments made in this case is clear, the giving of some items of value in an interim settlement that did not provide for immediate entry by the ANDA filer might not harm competition. In order to allow for consideration of arrangements that fall outside the type used in this case, the order would permit consideration of specific arrangements where the agreement is presented to the court hearing the patent infringement case in connection with a stipulation for a preliminary injunction. In this context, the order would allow the agreement if the following conditions are met:

- Respondent provides notice and information both to the Commission and the court as follows: (1) Respondent must provide the court, along with the joint stipulation for permanent injunction and the proposed agreement, a copy of the Commission's complaint and order; (2) at least 30 days before submitting the stipulation to the court, Respondent must provide written notice (as set forth in Paragraph VI of the order) to the Commission; and (3) Respondent does not oppose Commission participation in the court's consideration of the request for permanent injunction; and

- Either: (1) the court issues a preliminary injunction order and the parties' agreement conforms to that order; or (2) the Commission determines that the agreement does not raise issues under Section 5 of the FTC Act.

Part VI of the proposed order sets forth the notification requirements and procedures required under the order. The proposed order also contains certain reporting and other provisions

(Parts VII, VIII, and IX) that are designed to assist the Commission in monitoring compliance with the order and are standard provisions in Commission orders.

VII. EVIDENCE ISSUE RELATING TO INVESTIGATIONAL HEARING TRANSCRIPTS

Your Honor's April 9, 2002, Order on Complaint Counsel's Motion for Clarification (hereinafter "Clarification Order") explained that the investigational hearing transcripts of Schering and Upsher were admitted during the hearing only as party admissions and were not to be used against the other party, because complaint counsel never asked that these investigational hearings be admitted as coconspirator statements. Clarification Order at 4. Your Honor is correct that we never asked that they be so admitted in open court.

Complaint counsel did, however, make an offer of proof for the investigational hearings under the coconspirator rule, as a ground for their admission, in a pretrial motion dated January 14, 2002. In that motion we argued, albeit with less than ideal emphasis, that all investigational hearing transcripts of Schering, Upsher, and AHP should be admitted on the theory that

> under Federal Rule of Evidence 801(d)(2)(E), any statements by a co-conspirator of a party during the course and in furtherance of the conspiracy also are admissible against a party as non-hearsay. In fact, the Commission has specifically applied the co-conspirator rule under the Federal Rules of Evidence to admit evidence from unnamed co-conspirators against respondents in proceedings before the Commission. *American Medical Association*, 94 F.T.C. 701, 957 (1979) ("AMA").

Complaint Counsel's Response to Respondents' Motion Concerning the Use of Transcript Excerpts at 5 n. 12 (hereinafter "Pretrial Motion").

We made this offer of proof more explicitly in our Motion for Clarification, dated March 29, 2002, where we wrote "we respectfully request that Your Honor . . . allow us to use the statements of one conspirator against the other, as contemplated by Federal Rule of Evidence

801(d)(2)(E) and endorsed by the Commission in the *AMA* case." Complaint Counsel's Motion, and Memorandum in Support of Motion, for Clarification of Evidentiary Ruling at 4-5 (hereinafter "Clarification Motion"). Based on complaint counsel's offers of proof in the Pretrial Motion and the Clarification Motion, we ask that the Schering and Upsher investigational hearing testimony be deemed "conditionally" admitted as coconspirator statements.

Following Your Honor's guidance in the Clarification Order that evidentiary challenges under the coconspirator doctrine "shall be raised in the post trial briefs" (Clarification Order at 6), complaint counsel respectfully request that the Schering and Upsher investigational hearing testimony be admitted in evidence under the coconspirator doctrine. The Clarification Order requires that the conditionally admitted evidence satisfy the elements of Rule 801(d)(2)(E),[191] which provides that evidence is non-hearsay if it arose "during the course and in furtherance of the conspiracy." Fed. R. Evid. 801(d)(2)(E).

The Schering and Upsher investigational hearing testimony comes within Rule 801(d)(2)(E), as interpreted by the Commission in *AMA*. Establishing a conspiracy for purposes of a civil antitrust case requires nothing more than evidence of an agreement.[192] Here, there is no dispute that Schering and Upsher entered into a written agreement, which lies at the heart of this case. CPF 198, 223. That agreement remains in force today, and the parties have continued to abide by its terms. Upsher, for example, did not compete with a generic K-Dur 20 product until

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[191] Clarification Order at 6.

[192] *See* 2 Julian O. Von Kalinowski, *Antitrust Laws and Trade Regulation*, § 26.02[2] at 26-32 to 33 (2001); *see also Tidmore Oil Co. v. BP Oil Co.*, 932 F.2d 1384, 1388 (11th Cir. 1991) (citing VI Phillip E. Areeda, *Antitrust Law*, § 1403 at 17) ("Courts use the words 'contract,' 'combination,' and 'conspiracy' interchangeably, and sometimes simply refer to an 'agreement.'").

September 1, 2001, the date specified in the agreement. CPF 224. No additional evidence is required to prove the conspiracy. Under the coconspirator doctrine, this testimony by the parties to the conspiracy, under oath and given during the Commission's investigation, is "admissible against all parties to the conspiracy." Clarification Order at 6. Furthermore, as long recognized by the Commission, investigational hearing testimony is considered reliable evidence and is therefore admissible for all purposes.[193]

CONCLUSION

For the foregoing reasons, complaint counsel respectfully request that Your Honor adopt complaint counsel's proposed findings of fact and conclusions of law.

Respectfully Submitted,

Karen Bokat

Karen Bokat
Philip M. Eisenstat
Bradley S. Albert
Elizabeth R. Hilder
Michael B. Kades
Markus H. Meier

Counsel Supporting the Complaint

Dated: May 13, 2002

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[193] *See The Hearst Corp.*, 80 F.T.C. 1011, 1016 (1972) ("[T]ranscripts resulting from an investigational hearing also constitute appropriate evidentiary material to support or oppose a summary decision motion. The thrust of [the Commission's summary decision rule] is to permit the use of material which has been obtained under oath and which is reliable data. Clearly transcripts from investigational hearings fall into this category of material and should be permitted under the rule.")

ORDER

I.

IT IS ORDERED that for the purposes of this Order, the following definitions shall apply:

A. "Respondent Schering" means Schering-Plough Corporation, its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Schering-Plough Corporation, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

B. "Respondent Upsher" means Upsher-Smith Laboratories, Inc., its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled by Upsher-Smith, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

C. "Commission" means the Federal Trade Commission.

D. "180-day Exclusivity Period" means the period of time established by section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(5)(B)(iv) (2002)).

E. "AB-rated Generic Version" means an ANDA found by the Food and Drug Administration to be bioequivalent to the Referenced Drug Product, as defined under 21 U.S.C. § (j)(8)(B) (2002).

F. "Agreement" means anything that would constitute an agreement under Section 1 of the Sherman Act, 15 U.S.C. § 1 (2002) or Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45 (2002).

G. "ANDA" means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j).

H. "ANDA Filer" means a party who has filed an ANDA with the FDA.

I. "ANDA First Filer" means the party whom the FDA determines is and remains entitled to, or eligible for, a 180-day Exclusivity Period which has not expired.

J. "ANDA Product" means the product to be manufactured under the ANDA that is the subject of the Patent Infringement Claim.

K. "Drug Product" means a finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients, as defined in 21 C.F.R. § 314.3(b).

L. "Effective Date" means the date of entering into the Agreement.

M. "Expiration Date" means 180 days after the date that the ANDA First Filer commences commercial marketing of (1) the ANDA Product, (2) the Reference Drug Product, or (3) any other AB-Rated Generic Version of the Reference Drug Product.

N. "FDA" means the United States Food and Drug Administration.

O. "NDA" means a New Drug Application, as defined under 21 U.S.C. § 355(b).

P. "NDA Holder" means: (1) the party that received FDA approval to market a Drug Product pursuant to an NDA, (2) a party owning or controlling enforcement of the patent(s) listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the "FDA Orange Book") in connection with the NDA, or (3) the predecessors, subsidiaries, divisions, groups and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (1) and (2) above (such control to be presumed by direct or indirect share ownership of 50% or greater), as well as the licensees, licensors, successors and assigns of each of the foregoing.

Q. "Patent Infringement" means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.

R. "Patent Infringement Claim" means any allegation made to an ANDA Filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA Product may infringe any patent held by, or exclusively licensed to, the NDA holder of the Reference Drug Product.

S. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

T. "Reference Drug Product" means the Drug Product identified by the ANDA applicant as the Drug Product upon which the ANDA Filer bases its ANDA.

U. "Relinquish" means abandon, waive, or relinquish.

V. "Sale of Drug Products" means the sale of Drug Products in or affecting commerce, as commerce is defined in section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44 (2002).

II.

IT IS FURTHER ORDERED that in connection with the Sale of Drug Products each Respondent shall cease and desist, directly or indirectly, from being a party to any Agreement resolving or settling a Patent Infringement Claim in which:

A. an ANDA Filer receives anything of value, and

B. the ANDA Filer agrees not to research, develop, manufacture, market, or sell, the ANDA Product for any period of time.

PROVIDED, HOWEVER, that nothing in this Paragraph shall prohibit a resolution or settlement of a Patent Infringement Claim in which:

(1) a Respondent is either the NDA Holder or the ANDA Filer;

(2) the value paid by the NDA Holder to the ANDA Filer as a part of the resolution or settlement of the Patent Infringement Claim includes no more than (1) the right to market the ANDA Product prior to the expiration of the patent that is the basis for the Patent Infringement Claim, and (2) the lesser of the NDA Holder's expected future litigation costs to resolve the Patent Infringement Claim or $2 million; and

(3) Respondent has notified the Commission, as described in Paragraph VI.

III.

IT IS FURTHER ORDERED that, when a Respondent makes or is subject to a Patent Infringement Claim in which such Respondent is either the NDA Holder or the ANDA Filer, Respondent shall cease and desist, in connection with the Sale of Drug Products, from being a party to any Agreement in which the ANDA Filer agrees to refrain from researching, developing, manufacturing, marketing, or selling any Drug Product that:

A. could be approved for sale by the FDA pursuant to an ANDA; and

B. is neither the subject of any written claim or allegation of Patent Infringement nor supported by a good faith opinion of counsel that the Drug Product would be the subject of such a claim or allegation if disclosed to the NDA Holder.

IV.

IT IS FURTHER ORDERED that each Respondent shall cease and desist, directly or indirectly, in connection with the Sale of Drug Products, with respect to which such Respondent is either an NDA Holder or the ANDA First Filer for the Reference Drug Product(s), from being a party to any Agreement in which:

A. one party is an NDA Holder and the other party is the ANDA First Filer for the Reference Drug Product, and

B. the ANDA First Filer is prohibited by such Agreement from Relinquishing, or is subject to a penalty, forfeiture, or loss of benefit if it Relinquishes, its right to the 180-day Exclusivity Period.

PROVIDED, HOWEVER, that nothing in this Section shall prohibit any Agreement where the following three conditions are all met:

(1) within twenty (20) days of the Effective Date of the Agreement, the ANDA First Filer commences commercial marketing of the ANDA Product, the Reference Drug Product, or any other AB-rated Generic Version of the Reference Drug Product;

(2) one of the following two conditions has been satisfied:

(a) the 180-day Exclusivity Period, if any, has been triggered and begun to run with respect to the ANDA Product; or

(b) within ten (10) days of the commercial marketing of a Drug Product other than the one subject to the ANDA, the ANDA First Filer has notified the FDA, in writing, that it will Relinquish any and all eligibility for, and entitlement to, a 180-day Exclusivity Period, if any, for the ANDA Product, beyond the Expiration Date; and

(3) Respondent has notified the Commission, as described in Paragraph VI.

V.

IT IS FURTHER ORDERED that, in any instance where a Respondent is a party to a Patent Infringement lawsuit in which it is either the NDA Holder or the alleged infringer ANDA Filer, such Respondent shall cease and desist, directly or indirectly, in connection with the Sale of Drug Products, from being a party to any Agreement in which:

A. the parties do not agree to dismiss the litigation,

B. the NDA Holder provides anything of value to the alleged infringer, and

C. the ANDA Filer agrees to refrain during part or all of the course of the litigation from selling the ANDA Product, or any Drug Product containing the same active chemical ingredient as the ANDA Product.

PROVIDED, HOWEVER, such an Agreement is not prohibited by this Order when entered into in conjunction with a joint stipulation between the parties that the court may enter a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, Fed. R. Civ. P. 65, if:

(1) together with the stipulation for a preliminary injunction Respondent provides the court the proposed Agreement, as well as a copy of the Commission's complaint, and Order in this matter;

(2) Respondent has notified the Commission, as described in Paragraph VI, least thirty (30) days prior to submitting the stipulation for a preliminary injunction;

(3) Respondent does not oppose any effort by the Commission to participate, in any capacity permitted by the court, in the court's consideration of any such action for preliminary relief; and

(4) (a) the court issues an order and the parties' agreement conforms to said order; or

(b) the Commission determines, at the request of Respondent, that entering into the stipulation would not raise issues under Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. Nothing in paragraph V shall be interpreted to prohibit or restrict the right of Respondent to unilaterally seek relief from the court (including but not limited to, applying for preliminary injunctive relief or seeking to extend, or reduce, the 30-month stay pursuant to 21 U.S.C. § 355(j)(5)(B)(iii)).

VI.

IT IS FURTHER ORDERED that each Respondent shall:

A. notify the Commission as required by Paragraphs II, IV, and V in the form of a letter ("Notification Letter") submitted to the Secretary of the Commission and containing the following information:

(1) the docket number and caption name of this Order;

(2) a statement that the purpose of the Notification Letter is to give the Commission prior notification of a proposed Agreement as required by this Order;

(3) identification of the parties involved in the proposed Agreement;

(4) identification of all Drug Products involved in the proposed Agreement;

(5) identification of all persons to the extent known who have filed an ANDA with the FDA (including the status of such application) for any Drug Product containing the same chemical entity(ies) as the Drug Product(s) involved in the proposed Agreement;

(6) a copy of the proposed Agreement;

(7) identification of the court, and copy of the docket sheet, for any legal action which involves either party to the proposed Agreement and relates to any Drug Product(s) containing the same chemical entity(ies) involved in the Agreement; and

(8) all documents which were prepared by or for any officer(s) or director(s) of Respondent for the purpose of evaluating or analyzing the proposed Agreement.

B. Submit the Notification Letter to the Secretary of the Commission at least thirty (30) days prior to consummating the proposed Agreement (hereinafter referred to as the "First Waiting Period").

C. If the Notification Letter is provided pursuant to:

(1) Paragraph II, representatives of the Commission may make a written request for additional information or documentary material (as if the

request were within the meaning of 16 C.F.R. § 803.20) prior to expiration of the First Waiting Period. If such a request for additional information is made, Respondent shall not execute the proposed Agreement until expiration of thirty (30) days following complete submission of such additional information or documentary material.

(2) Paragraphs IV or V, Respondent may execute the proposed Agreement upon expiration of the First Waiting Period.

Early termination of the First Waiting Periods in this Paragraph VI may be requested from the Director of the Commission's Bureau of Competition.

VII.

IT IS FURTHER ORDERED that each Respondent shall file a verified written report within sixty (60) days after the date this Order becomes final, annually thereafter for five (5) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require, setting forth in detail the manner and form in which Respondent intends to comply, is complying, and has complied with this Order. Each Respondent shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with this Order.

VIII.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least thirty (30) days prior to any proposed change in Respondent such as dissolution, assignment, sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in Respondent that may affect compliance obligations arising out of this Order.

IX.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order and subject to any legally recognized privilege or immunity, and upon written request with reasonable notice to Respondents, Respondents shall permit any duly authorized representative of the Commission:

A. Access, during office hours and in the presence of counsel, to all facilities, and to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in their possession or under their control relating to compliance with this Order; and

B. To interview officers, directors, employees, agents, and other representatives of Respondents, who may have counsel present regarding such compliance issues.

X.

IT IS FURTHER ORDERED that this Order shall terminate ten (10) years from the date this Order becomes final.

Appendix B

FTC Witnesses

Martin Adelman

Martin Adelman is a professor of patent law at George Washington University; he has taught there for four years in addition to being the director of the Dean Dinwoodey Center for Intellectual Property Studies. Dr. Adelman is also a professor emeritus at Wayne State University, where he taught patent, antitrust, copyright and tort law for 25 years prior to his current job. He is a member of the ABA, the Michigan Bar, the American Intellectual Property Law Association, and ATRIP, an international association of intellectual property professors. Since 1977, he has co-authored *Patent Law Perspectives*, an eight volume compendium of patent law and practice. He is an expert in patent law and patent practices.

Max Bazerman

Professor Bazerman is a professor at Harvard Business School and maintains an affiliated appointment with the Program on Negotiation at the Kennedy School of Government. As an independent consultant, he leads programs on negotiations and decision making for private corporations. Since receiving his Ph.D. in organizational behavior from Carnegie Mellon in 1979, Dr. Bazerman has been a professor at various other universities including the University of Texas in Austin, Boston University, and Massachusetts Institute of Technology. He has published ten books, including a field standard textbook titled *Judgment in Managerial Decision Making*. Dr. Bazerman is a fellow of the American Psychological Association, the American Psychological Society, and the Academy of Management. He is an expert in negotiations and dispute resolution.

Timothy F. Bresnahan

Professor Bresnahan is a professor of Economics at Stanford University, a position he has held since 1979. He is an established industrial organization and empirical economist, and has published numerous articles about patent intensive industries, entry into unconcentrated and monopoly markets, and the valuation of new products. His extensive antitrust expertise includes two years as the chief economist at the Antitrust Division in the Department of Justice. He has been an editor of leading economic and industrial organization journals, including the leading economic journal and the official journal of the American Economic Association, *American Economic Review*, as well as the *Rand Journal of Economics*, *Journal of Industrial Economics*, and *Quarterly Review of Economics*. He is an expert in the economics of patent settlement, litigation, and mediation.

James Egan

James Egan is senior vice president for licensing and corporate development at Novirio Pharmaceuticals, a pharmaceutical company that specializes in developing anti-viral drugs of

different types. He is responsible there for all mergers and acquisitions, strategic planning, licensing, product acquisitions, product dispositions, and constructing the strategic and commercial operating plans. Before his tenure at Novirio, Mr. Egan was employed by various pharmaceutical companies. He worked for Searle, beginning in 1993, and was promoted to senior director of licensing and business development in 1995, a position he held until he left the company in 2000. At Searle, Mr. Egan was responsible for in-licensing, out-licensing and platform and enabling technology evaluation. He found and negotiated global business opportunities at the company, for products in different pharmaceuticals classes including cardiovascular and anti-infectives.

Dean Goldberg

Dean Goldberg is Vice President of Clinical Pharmacy Management for United Healthcare, where he has also held positions as the Director of Therapeutic Outcomes Research for Applied Healthcare Informatics and Director of Clinical Pharmacy Management with United Healthcare. United Healthcare sells health benefit products, including health insurance, health plan administration, prescription drug insurance, and management of prescription drug insurance plans. Mr. Goldberg has worked in the pharmaceutical industry since receiving his doctorate in pharmacy, from the University of Minnesota. From 1989 to 1996, Mr. Goldberg worked in various pharmacy management positions for Diversified Pharmaceutical Services, a large pharmacy benefits manager.

Joel E. Hoffman

Joel E. Hoffman is a practicing lawyer who has had extensive experience since 1964 representing and advising business clients on matters of FDA regulatory law, including the Hatch-Waxman Act, since its enactment in 1984. He teaches FDA regulatory law as an adjunct professor of law at George Mason University Law School and Franklin Pierce Law Center; he has been an invited presenter at numerous Continuing Legal Education programs on FDA regulatory law. Mr. Hoffman received his law degree from Yale University Law School in 1960.

Dr. Nelson L. Levy

Dr. Nelson L. Levy received his M.D. from Columbia University in 1967, served as a medical resident at Duke University from 1972-73, and then later received his Ph.D. in immunology from Duke in 1973. He conducted research at the National Institutes of Health in the areas of virology and immunology prior to receiving his Ph.D. He later became an associate professor with tenure at Duke University (from 1973-81), instructing medical and graduate students.

Dr. Levy entered the private sector in 1981 as vice president of pharmaceutical research for Abbott Laboratories. He then formed CoreTechs in 1984, an organization involved in providing consulting services to the healthcare and pharmaceutical industries, and aiding

developing companies to evaluate and market their technologies. From 1992-93, Dr. Levy was CEO of Fujisawa Pharmaceutical Company's U.S. subsidiary, with responsibility for all aspects of pharmaceutical development. He returned to CoreTechs in 1993, where he presently serves as its Chairman and CEO, continuing to provide consulting services to the pharmaceutical and healthcare industries, and developing companies. Dr. Levy serves on the boards of directors and scientific advisory boards for several pharmaceutical and biotech companies.

Mukesh Patel

Mukesh Patel is the senior director of business and commercial development at Otsuka America Pharmaceutical Company, where he has worked for the last year. His responsibilities involve the licensing of in-technology and products. Prior to his time at Otsuka America, Mr. Patel was employed by Kos Pharmaceuticals from 1991 to 2001. At the time of his departure from Kos, Mr. Patel was the vice president of licensing. Mr. Patel is a licensed pharmacist and has a master's degree in medicinal chemistry from Loughborough University of Technology in the United Kingdom.

Larry Rosenthal

Larry Rosenthal is Executive Vice President of Sales and Marketing for Andrx Pharmaceuticals, Inc. He has held this position since the start of his employment there, in January 1999. Andrx manufactures generic and innovator drug products. Prior to his employment with Andrx, Mr. Rosenthal was the vice-president of sales and marketing at Teva, where he worked from approximately 1986 until 1999. Teva manufactures primarily generic drugs.

J. Russell Teagarden

Mr. Teagarden is the Vice President of Clinical Practices & Therapeutics and the Vice President of Clinical Analysis & Outcomes Research for Merck-Medco, where he has been employed for the past eight and one-half years. He is currently a visiting scholar at the National Institute of Health in the field of Clinical Bioethics. Mr. Teagarden earned a degree in pharmacy from the University of Illinois, and a Master's degree in research methodologies from the Loyola University in Chicago.

Appendix C

Glossary of Terms

A. FDA/Hatch-Waxman Terms

1. **ANDA** - Abbreviated New Drug Application. An applicant seeking to market a generic version of a pioneer drug may submit an abbreviated new drug application. Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA), an applicant is no longer required to submit safety and effectiveness data, but instead may rely on the FDA's prior findings of safety and efficacy of the referenced drug product, so long as it can demonstrate that its generic drug is bioequivalent to the referenced drug product.

2. **Bioequivalent** - A generic drug is bioequivalent to a referenced drug product when (1) it has the same active ingredients as its branded counterpart, and (2) the rate and extension of absorption of its active ingredients fall within established parameters when compared to that of the referenced drug product.

3. **NDA** - New drug application. Under the FDCA, any applicant seeking to market a "new" or pioneer drug must first obtain FDA approval through the filing of a new drug application. An NDA applicant is required to provide, among other items, "full reports of the investigations" that demonstrate a drug product to be safe and effective for its intended use. The NDA applicant is required to submit to the FDA information on any patent covering the drug, or any method of using the drug for treatment of disease, for which a claim of patent infringement could reasonably be asserted against an unauthorized party. The FDA then lists the approved drug and related patents in its publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the "Orange Book."

4. **Orange Book** - Alternative name for the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations." The publication identifies drug products approved by the FDA on the basis of safety and effectiveness, and includes a list of relevant patents for each NDA. Inclusion of a product on the list creates no presumption as to the validity of its relevant patents.

5. **Paragraph IV Certification** - The ANDA applicant must provide a certification with respect to each patent listed in the Orange Book. A paragraph IV certification asserts that "such patent is invalid or will not be infringed" by the manufacture, use, or sale of the drug product for which the ANDA is submitted.

6. **Successful Defense Regulation** - Regulation promulgated in 1994 by the FDA, requiring the first ANDA applicant with a paragraph IV certification to successfully defend patent litigation over patents listed in the Orange Book for the

referenced drug product as a prerequisite for the applicant to be eligible for the 180-day exclusivity period. This regulation was challenged and questioned in the Mova case, and was subsequently abandoned by the FDA in June 1998, after two court of appeal decisions holding that the FDA's imposition of the requirement was improper.

7. **Tentative Approval of ANDA** - After all components of an ANDA are found to be acceptable, an approval or tentative approval letter is issued to the applicant. If the approval occurs prior to the expiration of the 180-day exclusivity or 30-month stay, a tentative approval letter is issued and final approval is delayed until the exclusivity or stay has expired. A tentative approval does not allow the applicant to market the generic drug product.

8. **30-month Stay** - Under the Hatch-Waxman Amendments, if the patentee, upon receiving notice of a Paragraph IV certification, files a patent infringement suit against the certifying ANDA filer within 45 days of such notice, FDA approval of the ANDA is automatically stayed until the earlier of (1) the expiration of 30 months from the patentee's receipt of notice of the Paragraph IV certification, (2) a final determination of non-infringement is entered in patent infringement litigation (currently interpreted by the FDA as including litigation involving any ANDA filer), or (3) the date the patents expire.

9. **180-day Exclusivity Right** - Under the Hatch-Waxman Amendments, as currently implemented by the FDA, the first applicant submitting an ANDA which contains a paragraph IV certification is protected from competition from subsequent generic versions of the same drug product for a period of 180 days after the earlier of the first commercial marketing of the first applicant's drug, or a decision of a court holding the patent that is the subject of the paragraph IV certification to be invalid or not infringed.

B. Product-related Terms

1. **Ethylcellulose (EC)** - A water insoluble polymeric material that is used extensively as a coating material for the controlled release of drugs. It is available commercially in a number of molecular weights and is classified accordingly by viscosity grade. Selection of a particular viscosity grade of EC is an important consideration in determining the release rates of a particular product.

2. **Hydropropylcellulose (HPC)** - A water soluble polymeric material that tends to increase the permeability of an EC coating and therefore the rate of the drug release HPC creates channels in an EC coating which allow for the release of a coated drug.

3. **Hypokalemia** - Potassium deficiency treated with potassium supplements such as K-Dur 20.

4. **K-Dur 20** - Brand name of widely-prescribed potassium chloride supplement sold by Schering.

5. **Klor-Con M20** - Upsher-Smith's generic equivalent of Schering's K-Dur 20.

6. **Niacin** - Class of pharmaceutical agents used for lowering cholesterol. This class includes Niacor-SR and Niaspan.

7. **Niacor-SR** - Upsher developmental product intended to be used as a sustained-release niacin product for the treatment of elevated cholesterol.

8. **Niaspan** - Sustained release niacin product of Kos Pharmaceuticals.

9. **'743 Patent** - Patent held by Schering that relates to specified amounts of coating materials (EC and HPC or polyethylene glycol) used in potassium chloride supplements. The coating slowly releases the potassium chloride over time, making it a sustained release product.