UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

COMPLAINT COUNSEL'S TRIAL BRIEF
[PUBLIC VERSION]

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Introduction

Generic drugs play a vital role in our nation's health care system. Priced substantially below their brand-name counterparts, generic prescription drugs offer consumers access to more affordable medications critical to their health and well-being. Policymakers at both federal and state levels have taken a variety of actions to promote consumer access to low-cost generic alternatives, in order to promote competition in pharmaceutical markets, aid consumers, and help contain rising health care costs.

These consumer benefits from generic drug competition, however, also mean lower profits for the makers of branded pharmaceuticals. This case is about one response to the threat posed by competition from lower-cost generic alternatives: paying generic rivals to delay their entry. We will prove that Schering-Plough Corporation paid would-be generic rival Upsher-Smith Laboratories $60 million, and American Home Products Corporation at least $15 million, in exchange for agreements not to enter the market with their respective generic products for several years. We will also show that these plainly anticompetitive agreements cannot be justified.

Schering sells a widely-prescribed potassium chloride supplement known as K-Dur 20. In 1995, the product manager for K-Dur advised company executives that ********** and that **********[1] Notwithstanding a patent covering K-Dur-20 that would not expire until 2006, she characterized the issues, objectives, and strategies regarding generic competition as follows:

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[1] CX 13, **********, at SP 003044 (Appendix D-1).

[redacted]

In this brief, we preview some of the evidence that will show why Schering expected generic entry well before the expiration of its patent, and why it was so important to Schering that it [redacted] Most important, we describe some of the evidence that we will offer to prove that the strategy that Schering used to achieve its objective to delay generic competition included paying its potential generic competitors, Upsher-Smith and American Home Products, to stay off the market for several years. We will also show that, in pursuing that strategy, the parties sought to avoid the appearance of a naked payment not to

[2] *Id.* at SP 003047-48.

compete, by attempting to depict Schering's payments as part of the fees paid to license certain products owned by Upsher-Smith and AHP.

This strategy was one that benefitted both Schering and its potential generic rivals, at the expense of consumers. Schering, the only seller of the popular and highly profitable K-Dur 20 potassium supplement tablet, purchased protection from generic entry. The price of that protection – tens of millions of dollars of its K-Dur 20 profits – was dwarfed by the hundreds of millions of dollars that it would lose if generic entry occurred. The would-be entrants were compensated while staying out of the market. All parties were aware that generic entry would cause Schering to lose more than a lower-priced generic could hope to earn. 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. Some of those losses become savings for consumers. In this case, however, Schering shared its profits with its competitors, and consumers lost the opportunity to reap the savings that generic entry offers.

There should be no dispute concerning either the threat to Schering's K-Dur 20 profits posed by generic entry, or Schering's incentive to pay for protection against such entry. Schering was vulnerable to generic competition on K-Dur 20 because it is the most widely-prescribed potassium supplement, and the patent covering K-Dur 20 is a relatively narrow one (claiming only a very particular type of extended-release mechanism). Furthermore, the congressional scheme for approval of generic drugs encourages companies to undertake challenges to patent validity or to design around valid patents.

Schering was acutely aware of the threat that a generic version of K-Dur 20 would pose.[3] In fact, only two months after generic entry finally did occur in September 2001, nearly [redacted] of new prescriptions for K-Dur 20 were filled with the generic product.[4] As the graph below depicts, [redacted]

[REDACTED]

The prospect of such substantial losses gave Schering a powerful incentive to use a portion of its profits to maximize the length of time to introduction of generic competition.

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[3] *See, e.g.*, CX122, [redacted]

[4] CX 5.

What is contested in this case is the nature and effect of the strategy that Schering chose to achieve its objective to delay generic entry. There is no dispute that Schering paid Upsher-Smith $60 million and AHP at least $15 million, and that each of these potential generic entrants agreed not to launch its product for several years. The evidence shows that respondents not only had ample incentives to enter into an agreement with a payment 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, and the parties' own testimony regarding the negotiations. All support the conclusion that Schering paid its competitors to leave the patent dispute unresolved and to instead set an entry date several years down the road.

The agreements are unlawful horizontal restraints of trade because of their inherently anticompetitive nature and the absence of any plausible justification. The likelihood of anticompetitive harm from agreements involving payments by a branded drug company to a potential generic rival in exchange for the would-be entrant's agreement to forestall entry is apparent. And the evidence regarding the agreements in this case confirms their anticompetitive character. Schering had a powerful incentive to pay its potential competitors to delay their entry and, when faced with the clear threat of generic entry, looked for a way to achieve that objective. Schering did not expect that its patent would prevent generic entry until it expired in 2006. And it was acutely aware – as were its potential generic competitors – of how quickly its K-Dur 20 profits would plummet once generic competition did arrive; obtaining any delay in generic entry would be extremely valuable. Upsher-Smith and AHP asked to be compensated for agreeing to forego entry. Schering, though it sought to avoid the appearance of a naked payment not to compete, recognized the need to provide such compensation, and made substantial payments to

both Upsher-Smith and AHP in exchange for their agreements not to enter the market, taking into account calculations of their estimated losses from delayed entry.

Because the nature of the agreements gives rise to an obvious inference of anticompetitive effects, they are unlawful *per se* unless they have a plausible justification. Respondents offer two purported justifications, but neither is plausible. First, their principal defense – that the $60 million payment to Upsher-Smith was for the Niacor-SR license – is contradicted by the evidence. There is ample evidence that Schering attempted to use licences to disguise the huge payment (though in the end it was poorly disguised). Indeed, it is not surprising that Schering's files contained a document, entitled ********** (CX 283) that contemplates **********

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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, no evidence suggests that their theories could explain the payments challenged in this case. In fact, the evidence shows the opposite: that these theories had nothing to do with the factors that actually motivated the agreements in this case. Since the asserted justifications are either pretextual or have no connection to the agreements here, the agreements lack any plausible efficiency justification and should be condemned as *per se* unlawful.

Moreover, as the Supreme Court made clear in *National Collegiate Athletic Assn. v. Bd. of Regents of the Univ. of Oklahoma*, 468 U.S. 85 (1984), and other cases, even where *per se*

treatment is not indicated, inherently anticompetitive restraints are condemned quickly under the rule of reason if the proffered justifications do not withstand scrutiny. Here, the proffered justifications plainly fail on that ground, and the agreements quickly can be found unlawful.

Even a more searching inquiry into market power and likely competitive effects under the rule of reason simply confirms that the agreements are unlawful. Schering's dominant position in the market and the competitive dynamic between branded pharmaceuticals and their generic versions show that the agreements plainly had the capacity to cause serious competitive harm. And the direct evidence of the effect of generic entry on sales of K-Dur-20 since Upsher-Smith entered with its generic product in September 2001 leaves no doubt that the delay of generic competition caused consumers to pay higher prices for 20 mEq potassium chloride products.

The agreements are also unlawful acts of monopolization, because Schering had monopoly power with respect to K-Dur 20, and it maintained that power through exclusionary conduct. The ample evidence that the availability of other potassium chloride products did not constrain Schering's ability to price its products far above what a generic would charge establishes that Schering had monopoly power with respect to K-Dur 20. And the agreements, because they were reasonably capable of maintaining that monopoly power and lack a legitimate justification, are unlawful exclusionary acts.

Finally, each of the challenged agreements also amounts to an unlawful conspiracy to monopolize, because in each case the parties entered into an agreement, and took actions in furtherance thereof, with the specific intent to maintain Schering's monopoly and share the monopoly profits. Statements and actions by each of the parties provide an ample basis from which to infer that they had a specific intent to preserve Schering's monopoly.

Respondents have submitted reports from a large number of expert witnesses to support what they contend is the proper way to assess whether the challenged agreements were actually anticompetitive. The tests respondents offer, however, are inconsistent and impossible to apply. Indeed, their own experts do not even try to apply them to the facts of this case. These tests do not provide a reliable way to evaluate whether agreements like the ones challenged here are anticompetitive. And, if adopted, they would effectively create a rule of *per se* legality, immunizing virtually any settlement of patent litigation, including settlements involving naked payments not to compete. Furthermore, respondents' suggestion that condemning the agreements in this case would threaten parties' rights to settle patent infringement litigation, or to purchase licenses in connection with such settlements, is unfounded. This case is about competitors using licenses as a cover for a payment not to compete.

Schering's agreements with Upsher-Smith and AHP denied consumers the benefits of a competitive marketplace, in which generic companies make decisions about whether to settle lawsuits, and when to enter the market, free from the influence of payments that distort their normal incentives to compete. Respondents' suggestions that Your Honor consider whether some hypothetical "consumer advocate" would find the entry dates that resulted from Schering's payments to be reasonable – given the risk that the potential generic entrants might lose the patent infringement cases – is simply an invitation to abandon the competitive system that antitrust law is designed to protect. In other words, it is "nothing less that a frontal assault on the basic policy of the Sherman Act." *National Society of Professional Engineers v. United States*, 435 U.S. 679, 695 (1978).

I. The Challenged Agreements

The Commission's complaint in this case challenges two separate agreements, one between Schering and Upsher-Smith, and another between Schering and American Home Products. The agreements were entered into in settlement of patent infringement suits brought by Schering against these companies after they sought approval to market a generic version of one of Schering's products. The agreements share many common features:

- substantial, up-front, non-contingent cash payments from Schering, the patent holder, to the alleged infringers ($60 million in the case of Upsher-Smith, and at least $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 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.

As discussed below, these agreements were unlawful payments not to compete that harmed consumers. Before addressing the specifics of these agreements, however, we begin with the industry context in which they arose.

II. The Commercial Realities of Generic Drug Competition in the Pharmaceutical Marketplace

In common parlance, a generic drug is one that contains the same active ingredients as its brand name counterpart. Within the pharmaceutical industry, "AB rated" generic drugs are most important to the competition and performance of the industry. An AB rated generic drug not only contains the same active ingredients as its brandname counterpart, also referred to as the "reference list drug," but is also "bio-equivalent" to the reference drug. Drug products are

considered bio-equivalent if there is no significant difference in their rate and extent of absorption compared to the reference drug, when administrated under similar conditions.[5] For the sake of simplicity, we use the term "generic drug" in this case to mean an AB rated generic drug.

Generic drugs generally are sold at substantial discounts off the price of the branded drug. Because of these price advantages, government officials and private purchasers have adopted policies to encourage or require pharmacists to substitute a generic drug for its branded equivalent. The result of this price difference and the ease of substitution has been a unique competitive dynamic between branded drugs and their generic counterparts, in which generic entry promptly causes a dramatic decline in the branded drug's sales. These basic economic realities of the pharmaceutical marketplace help to explain why companies may engage in tactics to delay generic entry, and why these tactics are so costly for consumers.

A. Generic Entry Generates Large Savings for Consumers

The effects of generic entry on consumer prices are well-documented: Generic entry causes prices to fall dramatically. 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 fall, sometimes to less than 50 per cent of the branded price.[6] A 1998 Congressional Budget Office Report estimates that in

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[5] *See* 21 U.S.C. § (j)(8)(B) (2001)

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

1994 alone, purchasers saved $8-$10 billion on prescriptions at retail pharmacies by purchasing generic drugs instead of the brandname product.[7]

There is evidence that the impact of generic entry is even greater today than in the early 1990s, when much of the economic research examining these issues was conducted. The evidence in this case bears that out: Upsher-Smith entered with Klor-Con M20 as the only generic version of K-Dur 20 at an immediate discount of approximately ••• percent off the brand price.[8]

B. Federal and State Policies Encourage Generic Entry

The benefits to consumers from generic drugs have spurred policy makers at both the federal and state levels to take actions to encourage generic entry.

1. Hatch-Waxman

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as "the Hatch-Waxman Amendments," to facilitate and encourage the market entry of generic drugs, while at the same time increasing incentives for pharmaceutical companies to invest in new drug development. The Amendments simplified the process for gaining FDA approval of generic versions of branded drugs, by allowing the generic applicant to reference the branded drug's safety and efficacy data. Under the Hatch-Waxman Amendments, generics file an Abbreviated New Drug Application ("ANDA") to establish that their product is bio-equivalent to its branded counterpart.

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[7] *Id.* at xiii, 13.

[8] Deposition of Robert Coleman, Director of Marketing, Upsher-Smith, at 26-27.

The scheme Congress established under the Hatch-Waxman Amendments encourages generic companies to undertake challenges to patent validity or to design around valid patents relating to branded drugs. It grants special status to the first company that seeks FDA approval for a generic alternative to a branded drug still covered by a patent, where that company certifies to the FDA that the patent in question is invalid or not infringed (known as the "Paragraph IV certification"). This "first filer" is eligible for a 180-day period of market exclusivity, during which it has the sole right to market a generic version of the brand-name drug. No other generic manufacturer may obtain FDA approval to market its product until the first filer's 180-day exclusivity period has expired.

This period of exclusivity is a valuable right. As described above, generic prices tend to fall as additional generic manufacturers enter the market.[9] Accordingly, the greatest returns are assured to the first entrant during its period of exclusivity.

2. State Substitution Laws

States have encouraged competition by generic drug products through laws that allow pharmacists to automatically substitute a generic drug for its branded equivalent, unless the physician directs otherwise. Some states require such substitution where the product is paid for by the state Medicaid plan or other public assistance program. Many health plans and other purchasers capitalize on the easy substitution created by state pharmacy laws, and encourage or insist upon use of generic versions of branded drugs when possible. This in turn creates an immediate market for generic entrants.

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[9] Congressional Budget Office Report, *supra* note 6, at 32.

C. The Branded Drug Maker Rapidly Loses Market Share When a Generic Enters

When a generic enters the market, it quickly takes market share away from its branded counterpart. Empirical research has demonstrated the rapid and dramatic effect of generic entry on branded companies' sales. Within the first full year after launch of a generic product, branded drugs lose an average of 44 percent of their market share to the generic product.[10] Thus, when a brandname drug is an important part of a pharmaceutical company's portfolio, generic entry can have a swift impact on its revenues and its bottom line.

The data on the impact of the introduction of Upsher-Smith's generic version of K-Dur 20, called Klor-Con M20, reflects this widely-recognized phenomenon. After Upsher-Smith's September 2001 launch of Klor-Con M20, new prescriptions rapidly shifted to the lower-priced generic. Within two months, Schering had lost to Upsher-Smith nearly ••• percent of all new prescriptions written for 20 mEq potassium chloride.[11]

D. The Unique Competitive Dynamic Between a Branded Drug and Its Generic Counterpart Creates Incentives for Companies to Enter into Agreements to Delay Generic Entry

While state substitution laws create a mechanism for relatively easy switching from a branded drug to its lower-cost generic counterpart, state laws do not permit the pharmacist to automatically substitute among branded drugs, or between a prescribed branded drug and a generic version of another branded drug. As a result, sales of generic drugs come at the expense of their branded counterparts, with little if any impact on the sales or price of other branded

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[10] Congressional Budget Office Report, *supra* note 6,. at xiii.

[11] CX 5.

products. Generic entry thus presents a unique competitive challenge for the branded drug manufacturer.

Furthermore, because generic drugs are priced so much lower than their branded counterparts, the returns to the brandname company from extending its monopoly almost always will exceed the potential economic gains to the generic applicant. As the FDA has observed, this creates incentives for companies to enter into agreements to delay generic entry, incentives that can be especially strong when the generic company holds market exclusivity rights that may create a barrier to all other potential generic competitors:

> [A] successful strategy to extend market exclusivity can mean tens of millions of dollars in increased revenue for an innovator firm. Under such circumstances, it can be mutually beneficial for the innovator and the generic company that is awarded 180 days of generic exclusivity to enter into agreements that block generic competition for extended periods. This delayed competition harms consumers by slowing the introduction of lower priced products into the market and thwarts the intent of the Hatch-Waxman Amendments.[12]

III. The Generic Threat to Schering's K-Dur 20

A. K-Dur 20 Was an Attractive Target for Potential Generic Competitors

Schering's K-Dur 20 is a potassium chloride supplement used by millions of Americans, particularly older persons suffering from high blood pressure and other chronic conditions. 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. Potassium chloride

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[12] FDA Proposed Rule Regarding 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873, 42882-83 (August 6, 1999).

supplements are necessary to alleviate potassium deficiency because such deficiency can cause muscle weakness and life-threatening cardiac conditions.

K-Dur 20 was an appealing target for generic entry because of its market dominance and the narrow nature of its patent protection.

1. K-Dur 20's Dominance

K-Dur 20 is the leading potassium chloride supplement in the United States. It has certain unique features that give it an advantage over the various other potassium supplements available to consumers. Until Upsher-Smith's entry in September 2001 with its generic product, Klor Con M20, K-Dur 20 was the only potassium chloride product in a 20 milliequivalent ("mEq"), extended-release dosage. The single 20 mEq dosage form means patients need fewer doses per day than would be required for alternative products. Fewer doses in turn can mean not only greater convenience, but also better patient compliance with the treatment prescribed by the physician. In addition, K-Dur 20 is a micro-encapsulated, extended-release product. Micro-encapsulation, which refers to the process by which the active ingredient (in the case of K-Dur 20, the potassium chloride) is coated, is designed to ensure a slow release of the potassium chloride, in order to minimize the adverse side effects (such as gastro-intestinal problems) that can otherwise result from a 20 mEq dosage of a potassium chloride product. K-Dur 20 unique characteristics made it the most widely-prescribed form of potassium supplement.

Throughout the early and mid-1990s, Schering raised prices and increased sales of K-Dur 20 despite the existence of alternative potassium chloride products. Schering's revenues and profits from K-Dur-20 increased. Both price increases and increasing sales volumes enhanced the profitability of the product.

The profitability of K-Dur 20 made it an attractive opportunity for a generic entrant, because a generic could do what the alternative potassium supplements could not. A lower-priced generic would quickly take sales from K-Dur 20. The general understanding of the impact of generic entry supported such a result, and Schering forecasted (correctly) that ••••••••••••••••••
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At trial, complaint counsel's economic expert, Stanford University Professor of Economics Timothy Bresnahan, will discuss 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. This evidence includes market forecasts from Schering, Upsher-Smith and AHP, which show that they all recognized that potential generic entrants had a unique ability to take away sales from Schering, forecasts that have been confirmed by the actual market effect caused by the introduction of Upsher-Smith's generic product in September 2001. Professor Bresnahan will explain how this evidence supports the conclusion that Schering had monopoly power in K-Dur 20.[13]

2. 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 20'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.[14] The patent concerns the coating

[13] CX 751, Expert Report of Timothy Bresnahan, at 23-26.

[14] CX 12, Patent No. 4,863,743 (Sept. 5, 1985).

used on the potassium chloride crystals that make up the K-Dur 20 tablet, and in particular the 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 claimed in the patent.

The narrow nature of this patent helps to explain why Schering predicted that generic entry would occur well before the patent's 2006 expiration date. [redacted][15] Taken as a whole, the evidence shows at a minimum that Schering did not expect that its '743 patent would prevent generic competition to K-Dur-20 through the expiration of the patent in 2006.

B. By 1997, Upsher-Smith and AHP Presented Significant Threats to K-Dur 20

Development of controlled-release oral pharmaceuticals has been an area of active interest for many companies in the pharmaceutical industry. In 1995, both Upsher-Smith and AHP sought FDA approval to market a generic version of K-Dur 20. Other companies have since filed ANDAs.

1. Upsher-Smith

Upsher-Smith filed an ANDA seeking FDA approval for a generic version of K-Dur 20 in August 1995. Upsher-Smith was the first to file an ANDA certifying that its product, Klor Con 20, did not infringe Schering's '743 patent. That certification meant Upsher-Smith was eligible for the 180-day exclusivity period provided under the Hatch Waxman Amendments.

Schering sued Upsher-Smith, claiming that its product infringed the '743 patent. Upsher maintained that its product did not infringe the patent, in particular because the coating it used:

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[15] CX 13, [redacted](Appendix D-1).

(1) was ethylcellulose with a viscosity of approximately 20 centipoise, and thus outside the patent (which claimed a viscosity of greater than 40 centipoise); and (2) did not contain any hydroxypropylcellulose or polyethylene glycol (ingredients that the '743 patent specifies).

As the litigation progressed, Upsher-Smith became a more imminent threat to Schering's K-Dur 20 profits. Upsher-Smith received tentative FDA approval[16] for its product in March 1997 and was making plans to launch its product in late 1997 or early 1998.[17] Upsher-Smith and IPC, a contract manufacturer that would have produced certain aspects of Upsher-Smith's generic K-Dur 20 product, agreed [redacted][18]

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[16] After the FDA concludes that all components of an ANDA are acceptable, it issues either an approval or a tentative approval letter to the applicant. A tentative approval letter is issued if the ANDA is otherwise approvable, but cannot receive final approval because either (1) the 180-day exclusivity period granted to a first ANDA filer has not expired; or (2) the statutory 30-month stay on FDA approval in cases of patent challenges has not expired. Under the Hatch-Waxman Amendments, the NDA holder with a non-expired patent, upon receiving notice of an ANDA filer's certification that it does not infringe a valid patent or the patent is invalid (the "Paragraph IV certification"), has 45 days to initiate a patent infringement suit against the applicant. If a patent infringement suit is filed within the 45-day window, 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 or invalidity is entered in the patent infringement litigation, or (3) the date the patent expires. Final approval is delayed until all exclusivity/30-month stay periods have expired. A tentative approval does not allow the applicant to market the generic drug product.

[17] CX 265, [redacted]

[18] *See, e.g.*, Troup Investigational Hearing at 64; CX 266, [redacted],USL 06747, USL 06748.

With a June 1997 trial date approaching, in May 1997 the parties began to negotiate a settlement. The evidence will show that Upsher-Smith's CEO, Ian Troup, told Schering he was willing to leave the patent dispute unresolved and accept an entry date several years in the future, but that he wanted to be paid $60-70 million in exchange.

On the eve of trial, the parties reached a settlement agreement.[19] Schering agreed to pay Upsher-Smith the $60 million it had requested, in three unconditional payments over a two-year period. Upsher-Smith in turn 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 series of licenses from Upsher-Smith to Schering, and 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.

2. AHP

American Home Products' ESI-Lederle, Inc. (hereinafter "AHP") unit filed an ANDA seeking FDA approval for a generic version of K-Dur 20 in December 1995.[20] 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.[21] Shortly thereafter, Schering brought a patent infringement suit against AHP.

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[19] CX 348, ********** (Appendix D-4).

[20] AHP has been withdrawn from the adjudication of this matter to permit the Commission to consider a proposed consent agreement.

[21] CX 419.

As in the case of Upsher-Smith, 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-Smith. Upsher-Smith, the first ANDA filer on K-Dur 20, was eligible for the 180-day exclusivity period under Hatch-Waxman. But recent court decisions had made it unclear whether Upsher-Smith had lost its exclusivity rights when it settled with Schering.[22] If Upsher-Smith retained it 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 in September 2001). There was, however, some possibility that AHP could win the patent suit and enter the market before March 2002.[23]

The parties settled the case in January 1998, with an agreement similar in several respects to the one Schering had entered into with Upsher-Smith six months earlier.[24] The agreement, which was finalized in June 1998, provided for payments from Schering to AHP of $15 million, with $5 million to be paid up front and an additional $10 million conditioned on AHP's obtaining tentative FDA approval by June 1999.[25] The agreement, like the one with Upsher-Smith, 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 variety of other restrictions barring AHP from supporting or promoting any generic competition to K-Dur 20. Finally, as in the case of Upsher-

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[22] *See* discussion at Section IV. D, *infra*.

[23] *See, e.g.*, Dey Investigational Hearing at 138; Schering Second Admissions at Nos. 133-135; *see also* Driscoll Investigational Hearing at 106-107.

[24] CX 474.

[25] CX 484, [redacted](Appendix D-6).

Smith, Schering purchased a license to certain products held by AHP, and Schering agreed to pay an additional AHP $15 million for those licenses.

IV. The Challenged Agreements Were an Anticompetitive Strategy Involving Payments to Delay Generic Entry

The key issue in dispute in this case is whether these agreements between competitors were for the purpose of delaying market entry, with the generics accepting payments in exchange for their agreement to delay. We will prove, through the agreements themselves and a variety of other evidence, that these were in fact payments for delay – delay that benefitted the parties but directly harmed consumers. The evidence will show that in both cases Schering's payments were compensation for the generics' agreeing to stay off the market for several years, and that those agreements harmed consumers, whether analyzed as horizontal agreements in restraint of trade or acts of monopolization.

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

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

The terms of the Schering/Upsher-Smith agreement directly link Schering's $60 million payment to Upsher-Smith's agreement to the 2001 entry date:

- *The consideration is expressly linked to Upsher-Smith's agreement to the entry date:* [redacted][26][redacted]

- *Upsher-Smith's obligation to abide by the entry date is conditioned on the payments:* [redacted]

[26] CX 348, [redacted] at USL 3188 (Appendix D-4).

[redacted]

- *The force majeure clause is consistent with payment for the entry date*: [redacted][27] [redacted]

2. Other Evidence Confirms That Schering Paid for the Entry Date

Complaint counsel will offer respondents' own business documents and other evidence to show that:

- Schering had the incentive and ability to pay Upsher-Smith to forgo entry until 2001, and Upsher-Smith had an incentive to agree to such an arrangement;
- Upsher-Smith negotiated for compensation in exchange for agreeing to stay off the market;
- Schering understood that it needed to compensate Upsher-Smith for staying off the market;
- The payment amount was calculated with reference to the impact on Upsher-Smith of giving up its challenge to Schering's patent; and
- Schering saw a problem with a naked payment and so sought to cast the payment in the guise of a purchase of licenses to various Upsher-Smith products.

For example, a June 1997 memorandum from a Schering Vice-President to the Schering Board of Directors concerning the proposed license agreement with Upsher-Smith states that Upsher-Smith was seeking [redacted]

[27] CX 348, at USL03184.

[redacted][28]

[redacted]

[redacted]

> [redacted]
> [redacted]
> [redacted]
> [redacted]
> [redacted][29]

Even more striking is another Schering document, entitled simply [redacted] which lays out the company's strategy for dealing with Upsher-Smith. It notes the need to [redacted]:

> [redacted]
> [redacted]
> [redacted][30]

In other words, payment would last only for so long as generics are kept out of the market. Once generic competition arrived, the "royalty stream" could stop:

> [redacted]
> [redacted][31]

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[28] CX 338, [redacted] (Appendix D-3).

[29] CX 338 at SP 12 00270.

[30] CX 283 at SP 018780 (Appendix D-2). Although Schering disclaims any knowledge as to the identity of the author or other circumstances surrounding this document, it does not dispute that it was produced from Schering's own files. *See* Schering's Response to Complaint Counsel's Corrected First Set Of Interrogatories (November 16, 2001), at 3.

[31] *Id.*

This document belies any claim that the payment was for anything other than an agreement not to compete. Indeed, the [redacted] specifically identified the masking mechanism that Schering actually chose to employ, noting that Schering could [redacted][32]

Finally, the document includes a calculation of the [redacted][33] Not surprisingly, Schering's agreement with Upsher-Smith tracked the model laid out in the [redacted] virtually to the penny. Schering arranged to pay Upsher-Smith $60 million over a two-year period – an amount that Professor Bresnahan will testify [redacted]. In exchange, Upsher-Smith agreed to forego competition with Schering until September 2001, and Upsher-Smith licensed a bundle of products to Schering.

3. 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 non-contingent payment – virtually unprecedented in size in the pharmaceutical industry – simply was further compensation for Niacor-SR. Our case-in-chief and anticipated rebuttal evidence will refute that argument. The evidence will show that Schering's $60 million payment to Upsher-Smith was not part of the

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[32] *Id.*

[33] *Id.* at SP 018781.

license fee for Niacor-SR. Not only do the agreements on their face show consideration was paid for the entry date, but also a variety of documentary and testimonial evidence, including an analysis by complaint counsel's pharmaceutical licensing expert, Dr. Levy, will demonstrate that:

- *The $60 million term of the agreement is anomalous in light of Schering's licensing practices and practices in the industry generally.* We will show that one term of the license – the $60 million non-contingent payment – greatly exceeded similar fees paid in other transactions by Schering, including those with far greater value than the products received under the Schering/Upsher-Smith agreement.[34] Furthermore, the agreement lacks the ordinary protections that would be expected in such an agreement, such as provision for substantial "milestone" payments upon completion of specific tasks. Indeed, the agreement does not require Upsher-Smith, the licensor, to do anything further.

- *The due-diligence process carried out by Schering in the evaluation of Niacor-SR was also anomalous, because, far from being extraordinarily diligent (as might have been expected in a deal where the amount of cash committed by Schering was unprecedented) Schering failed to follow the procedures ordinarily followed by Schering and those generally followed in the pharmaceutical industry.* A single employee, James Audibert, carried out the purported due-diligence in less than five days.[35] 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.[36]

- *The behavior of Schering and Upsher-Smith after execution of their agreement was inconsistent with the respondents' contention that they were serious about Schering's development of Niacor-SR.* The time lines that were presented to the Schering Board of Directors, after the "due diligence," 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.[37] The evidence shows no such effort was made. In addition, there was almost no communication

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[34] CX 753, Expert Report of Nelson Levy, at FTC 0020527-34; CX 1251; CX1253; CX 799, Expert Report of Walter Bratic, at Exhibit 6.

[35] *See, e.g.*, Investigational Hearing of James M. Audibert, at 31-32.

[36] *Id.* at 89-91.

[37] CX 338, [redacted] (Appendix D-3).

between Schering and Upsher-Smith regarding Niacor-SR after execution of the agreement, which would have been unusual if the parties had a sincere interest in the development of a pharmaceutical product.[38]

In addition, Professor Bresnahan will discuss evidence that shows that Schering was unwilling to make any non-contingent payment for another niacin product that Schering believed was equal to or better than Niacor-SR. He will also describe the evidence that Upsher-Smith contacted 49 companies in an effort to license the rights to Niacor-SR. Most showed no interest, and none offered a non-contingent payment. On the basis of this and other evidence, he concludes that ••• [39]

The evidence with respect to the Niacor-SR license is not – as respondents claim – offered to show that, given 20-20 hindsight, the license was not worth the $60 million that Schering paid. Rather, the fundamental point is that Schering's anomalous behavior – paying extraordinarily large, non-contingent payments without the type of due diligence that would ordinarily be conducted, and then virtually ignoring the product afterward – points to the same conclusion as the agreement terms and the contemporaneous business documents: that the Niacor-SR license arrangement was a veil for compensating Upsher-Smith for agreeing to stay off the market until 2001.

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

The link between the payment and the entry date in Schering's agreement with AHP is even clearer than in the case of Upsher-Smith. On its face, the agreement ties the compensation

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[38] *See e.g.* CX 753, Expert Report of Nelson Levy, at 31-32; CX 796, CX 1113.

[39] CX 751, Expert Report of Timothy Bresnahan, at 27-31.

to AHP directly to the length of time AHP forgoes entry once the FDA has approved its product.

[redacted][40] In other words, under the agreement, AHP would get more money the earlier it established it was a concrete threat to Schering's monopoly.

Because the agreement so clearly shows that Schering paid AHP for the future entry date, we need not inquire into Schering's additional $15 million payment for the licenses to a bundle of AHP products. It is sufficient that Schering paid at least $15 million for delay.

2. Other Evidence Confirms That Schering Paid AHP for the Entry Date

There is a variety of evidence that confirms what the terms of the agreement show. For example:

- AHP, like Upsher-Smith, wanted to be paid to give up its challenge to Schering's patent and to forestall introduction of its generic product, and it proposed a settlement whereby Schering would compensate it for agreeing to delay its entry.[41]
- The amount paid to AHP was proportional to what AHP thought it would forgo by not entering the market sooner.[42]

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[40] CX 484 [redacted] (Appendix D-4).

[41] *See, e.g.*, CX 459 [redacted] at AHP 05 00190 [redacted]

[42] *See, e.g.*, Dey Investigational Hearing at 137, 139, 143.

- AHP executive Dr. Dey testified that he may have been willing to accept an earlier entry date in exchange for forgoing some of Schering's up-front money.[43]

- Mr. Driscoll of Schering testified that he settled to avoid a possible negative result in the patent suit.

C. The Agreements Harmed Consumers.

If Schering's $60 million and $15 million payments were not for license rights, there is little doubt what they *were* for: to delay generic entry. As such, these agreements plainly harmed consumers, in violation of the antitrust laws.

To begin with, as discussed earlier, it is virtually undisputed that generic entry means lower prices for consumers. The evidence will show that ••• percent of customers have purchased generic K-Dur 20, at half the price of Schering's branded product, since generics were introduced into the market. Every day that generic entry has been postponed, therefore, is a day consumers paid higher prices.

As complaint counsel's economic expert, Professor Bresnahan, will explain, however, what is good for consumers is not so good for Schering and its generic competitors.[44] With respect to the ••• percent of K-Dur sales lost by Schering as a result of generic entry, Upsher-Smith (because it charges lower prices) has captured some, but not all, of the profits that Schering otherwise would have earned. The rest has been "lost" to consumers. As Professor Bresnahan will explain, this "lost" profit gives the parties – particularly in the case of a highly profitable drug like K-Dur 20 – a strong incentive to agree to delay competitive entry, extend the period of monopoly profits, and then split the profit among themselves.

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[43] *See, e.g.*, Dey Investigational Hearing at 141-142.

[44] *See* CX 751, Expert Report of Timothy Bresnahan.

Professor Bresnahan will testify that the parties acted in accordance with these incentives in the present case. As discussed earlier, Professor Bresnahan has concluded that [redacted]

Professor Bresnahan also has considered the post-hoc explanations provided by the respondents' experts and found none of them applicable to the circumstances of this case. Instead, his economic analysis confirms what common sense suggests, which is that Schering did not pay something for nothing. If Schering thought that, through litigation, it was likely to achieve a better outcome than generic entry in September 2001, it would not have paid Upsher-Smith $60 million to achieve that same result. Similarly, if Schering thought that Upsher-Smith would agree to settle for a September 2001 entry date without a payment, it would have done so. Schering's payment in this case only makes sense if it secured a later entry date than it believed it could obtain without the cash.

The complexity of the models that respondents' economists propose reflects their need to obscure the plain facts about respondents' behavior. But respondents' efforts are in vain: as the evidence at trial will show, the plain facts are that these competitors entered into agreements for the purpose of postponing competition in the K-Dur 20 market; and the expected and likely consequence of this delay was to enrich the parties, at the cost of millions of dollars of harm to consumers.

D. Schering's Agreement with Upsher-Smith Had Additional Anticompetitive Effects

Schering's agreement with Upsher-Smith not only affected entry by Upsher-Smith, but also served to create an obstacle to entry by other potential generic competitors. This effect on third parties arose because Upsher-Smith was the first to file an ANDA certifying that it did not infringe Schering's patent on K-Dur 20. Thus, Upsher-Smith was eligible for the 180-day market exclusivity period provided by the Hatch-Waxman Amendments. The agreement, by securing Upsher-Smith's promise to forestall its entry, ensured that Upsher-Smith would not trigger its Hatch-Waxman exclusivity right. Until that right expired, additional entry would be blocked, unless Upsher-Smith chose to waive this highly valuable exclusivity right.

At the time of Schering's June 1997 agreement with Upsher-Smith, there was some uncertainty about whether this blocking effect would actually arise. The focus of the uncertainty was the continued viability of a 1994 FDA regulation that a first filer had to successfully defend a patent infringement suit to qualify for the 180-day exclusivity period (application of which would mean that a settling first filer would not block entry by other generics). The "successful defense" requirement had been challenged as contrary to the plain language of the statute, and in January 1997, the court in *Mova Pharmaceuticals Corp. v. Shalala*, 955 F. Supp. 128 (D.D.C. 1997), agreed. By the time Schering settled with Upsher-Smith in June 1997, it appeared that the successful defense requirement might be on the way out.

Shortly after the settlement, however, the July 1997 decision in another suit, *Granutec, Inc. v. Shalala*, 1997 WL 1403894 (E.D.N.C. 1997), *rev'd*, 1998 U.S. App. LEXIS 6685 (4th Cir. 1998), increased the likelihood that Upsher-Smith's settlement with Schering would mean that it would lose its claim to the 180-day exclusivity period. This raised the possibility that AHP could

enter the market before Upsher-Smith. In addition, during this period FDA began to take the position that a court victory by a subsequent ANDA filer (such as AHP) would trigger the first filer's exclusivity period.[45] In that case, even if Upsher-Smith retained its exclusivity, an AHP victory in the patent case would mean AHP could enter the market 180 days from the date of its victory. Schering's agreement with AHP provided some assurance that generic entry would not occur until 2001 regardless of developments in the courts.

Ultimately, the demise of the successful defense requirement became clear.[46] Upsher-Smith continued to enjoy rights to the exclusivity period. When AHP received tentative FDA approval in May 1999, it was not eligible for final FDA approval because there was an earlier filer (Upsher-Smith) who possessed unexpired rights to180 days of market exclusivity.[47]

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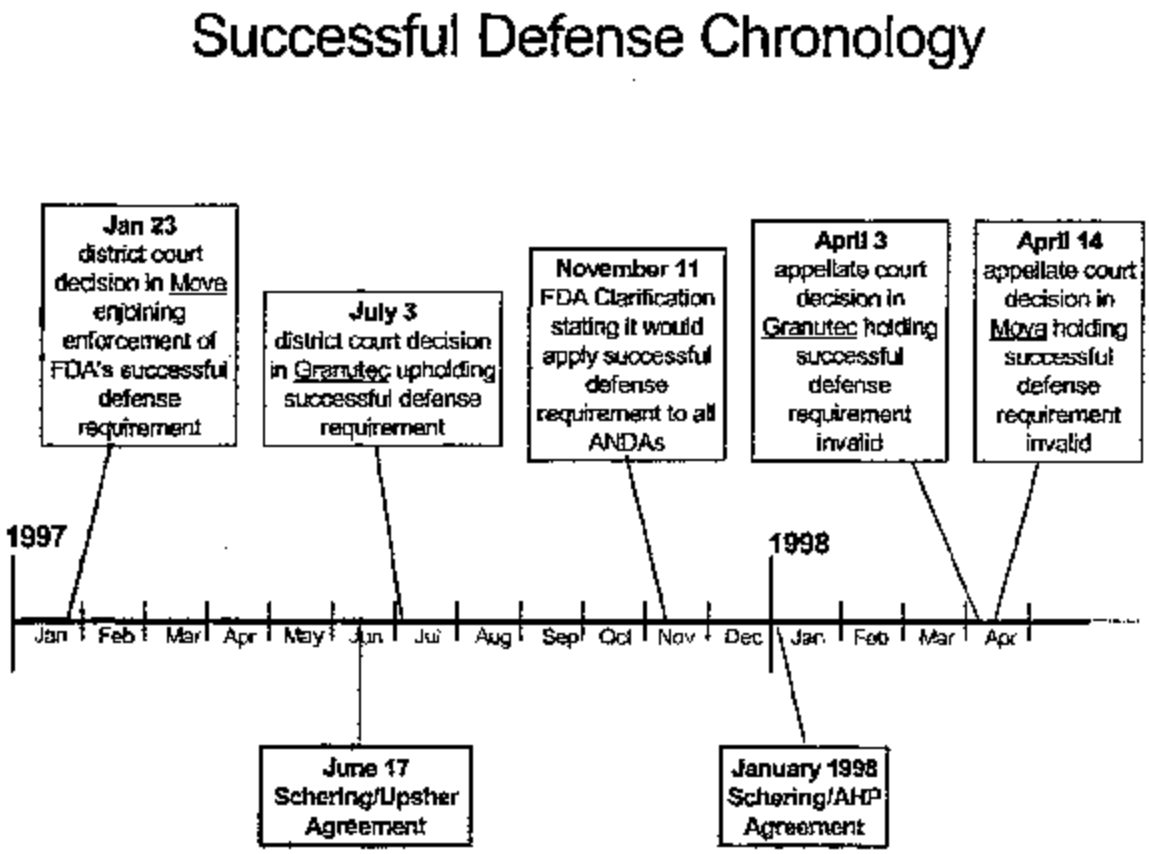
[45] *See* CX 752, Expert Report of Joel E. Hoffman, at 16-18.

[46] *Mova* was upheld on appeal (140 F.3d 1060 (D.C. Cir. 1998)), and the contrary district court decision in *Granutec* was reversed by the Fourth Circuit. *Granutec, Inc. v. Shalala*, 1998 U.S. App. LEXIS 6685 (4th Cir. 1998).

[47] CX 482, [redacted] at SP 13 00799.

The time line below depicts the chronology of legal developments regarding the successful defense requirement in the context of the challenged agreements:



In sum, while there was uncertainty concerning the effect of settlement on Upsher-Smith's continued right to the exclusivity period at the time it was entered into, Schering's agreement with Upsher-Smith eliminated the possibility that Upsher-Smith would launch its product and trigger its exclusivity period prior to September 2001. In this respect, the agreement can be seen

as a way of purchasing some insurance against entry by all generic applicants. Even if it was not a perfect barrier to generic entry,[48] it provided Schering with a significant degree of protection.

E. The Agreements' Restraints on Entry with a Non-Infringing Product Also Evidence the Scheme to Delay Generic Entry

The plain language of each of the challenged agreements bars entry with *any* generic version of K-Dur 20, not merely the allegedly infringing product that was the subject of the patent litigation. Paragraph 3 of the Schering/Upsher-Smith Agreement states in part that:

[redacted][49]

[redacted][50]

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[48] There might still have been the possibility that another applicant could trigger Upsher-Smith's exclusivity by obtaining a favorable court decision in a patent challenge brought by Schering, or even at least a theoretical possibility that Upsher-Smith could waive its exclusivity rights.

[49] CX 348, at USL03187 (Appendix D-4) (emphasis added). [redacted]

[50] CX 484, Para 3.1(a)(iii), Para. 1.2 (Appendix D-6).

[redacted]

[redacted][51]

Respondents have attempted to defend these restrictions by suggesting that they did not intend to prevent competition from non-infringing products. But the presence of such clear language in these detailed legal contracts – particularly when viewed in light of the evidence that Schering's objective was to delay generic competition as long as possible – obviates any need for Your Honor to consider respondents' suggestions that this broad language does not means what it says. These provisions are not only anticompetitive standing alone, but are also further evidence that the challenged agreements were a scheme to delay generic competition.

V. The Agreements Are Unlawful Horizontal Restraints of Trade

Schering's agreements with Upsher-Smith and AHP included payments not to compete that had the purpose and effect of assuring the delay of generic competition. The direct consumer harm that flows from delayed generic entry is beyond dispute. Consequently, the agreements are unlawful horizontal restraints of trade.

The legal principles to be applied to the agreements are straightforward. Agreements between competitors or potential competitors that govern the way they compete with one another are horizontal restraints of trade.[52] Schering's agreements -- with two companies that were seeking to market low-cost generic products that would compete with Schering's K-Dur 20

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[51] CX 484 at 5 (Appendix D-6) [redacted] CX 484, at Article III, Para. 3.1(a)(iii).

[52] *See, e.g., Nat. Collegiate Athletic Ass'n. v. Bd. of Regents of the Univ. Of Okla.*, 468 U.S. 85, 99 (1984) [hereinafter *NCAA*].

potassium supplement -- are thus horizontal restraints. Such restraints are unlawful if they unreasonably limit competition.

The antitrust inquiry into the reasonableness of a restraint turns on the competitive significance of the conduct in question. The central question is 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 efficiency and make markets more rather than less competitive."[53]

When the anticompetitive character of the restraint is clear, the restraint is deemed *per se* unreasonable, unless there is sufficient reason to believe it might have offsetting benefits to competition. Where there is a plausible justification for the restraint, or where the anticompetitive character of the restraint is not sufficiently clear, then a closer look is needed to assess its likely competitive effects. The extent of additional scrutiny needed to assess the competitive significance of the restraint will vary, depending on the nature and character of the conduct in question and the strength of justifications offered. As the Supreme Court explained in its most recent horizontal restraints case, *California Dental Association v. FTC*, 526 U.S. 756, 780-81 (1999):

> there is generally no categorical line to be drawn between restraints that give rise to an intuitively obvious inference of anticompetitive effects and those that call for more detailed treatment. What is required, rather, is an inquiry meet for the case, looking to the circumstances, details, and logic of a restraint."

The purpose of the inquiry, however, always is to "form a judgment about the competitive

[53] *Broadcast Music, Inc. v. CBS*, 441 U.S. 1, 19-20 (1979) [hereinafter *BMI*].

significance of the restraint.[54]

As is discussed below, Schering's agreements with Upsher-Smith and AHP are plainly anticompetitive in nature. Accordingly, they can be summarily condemned unless they appear to be capable of producing off-setting procompetitive benefits. The justifications asserted by the parties are pretextual, implausible, or are not supported by the evidence, and thus can be rejected. On that basis alone, the agreements are unlawful. Moreover, because of the clear impact that generic entry has on the prices that consumers must pay, payments to delay generic competition cause serious and direct consumer harm. Thus, the agreements also are illegal under a more searching rule of reason inquiry. Finally, the agreements are unlawful even if there is uncertainty regarding whether and when potential competitors would actually enter the market, and without regard to the relative merits of the parties' positions in the underlying patent cases.

A. The Agreements Give Rise To An Obvious Inference of Anticompetitive Effects

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 enter the market until a date several years in the future. In light of the economic realities of generic drug competition in the pharmaceutical industry, common sense suggests that the agreements challenged here are by their very nature anticompetitive. That is, payment by a branded drug maker to a potential generic rival in exchange for the would-be entrant's agreement to forestall entry is a practice that would "always or almost always tend to restrict competition

[54] *NCAA*, 468 U.S. at 103, *quoting Nat'l Soc'y of Prof. Eng's v. United States*, 435 U.S. 679, 692 (1978).

and decrease output."[55] Indeed, courts faced with agreements in which a branded drug maker pays the allegedly infringing, would-be generic entrant have repeatedly observed that such payments logically indicate that the payment was for delayed generic competition.[56]

Application of basic economic principles to the agreements leads to the same conclusion. Where a potential generic entrant threatens the monopoly profits of the brand drug company, the payment by the band company to the allegedly-infringing generic firm in order to secure a promise to stay off the market is inherently likely to injure competition. 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 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 monopoly profits. We can confidently predict that the payment will result in an entry date that is later than either party expected from the litigation, or than would occur in a settlement without a payment.

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[55] *BMI*, 441 U.S. at 19-20.

[56] *See, e.g., Andrx Pharm., Inc. v. Biovail Corp.*, 256 F.3d 799, 809-10, 813 (D.C. Cir. 2001) (explaining that it is reasonable to conclude that absent the agreement, generic would have entered the market and that the brand's payments were in return for the generic's agreeing to delay marketing its product); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682 (E.D. Mich. 2000), *appeal docketed*, No. 00-2483 (6th Cir. Dec. 19, 2000) (finding agreement *per se* unlawful); *In re Ciprofloxacin*, 166 F. Supp. 2d 740, 750 (E.D.N.Y. 2001) (noting logic in allegation that payment was for delay in generic entry and intended to share monopoly returns on the drug, given incentives in Hatch-Waxman context); *Biovail Corp. Int. v. Hoechst A.G.*, 49 F. Supp. 2d 750, 766 (D. N.J. 1999) (explaining that a reasonable trier of fact could conclude that an agreement between two competitors to delay running of the Hatch-Waxman exclusivity period for the purpose of keeping another competitor out of the market is an unreasonable restraint of trade or a willful attempt to maintain or obtain a monopoly).

There is ample evidence to demonstrate that this theory, which rests on established economic principles relating to the consumer effects of entry into monopoly markets and dispute resolution, is sound in the particular circumstances of this case. For example, the trial will show that the parties had obvious incentives to make and accept a payment to delay generic competition. In the case of the Upsher-Smith agreement, the possibility that it would block entry by other generic manufacturers provided additional incentive. Each of the potential generic entrants -- Upsher-Smith and AHP -- made it clear that they expected to be paid to end the litigation, and in particular that they wanted to be compensated for the revenues they would lose by agreeing to refrain from entry; and Schering, though it sought to avoid the appearance of a naked payment not to compete, recognized the need to provide such compensation. The inherently anticompetitive nature of these agreements is apparent. Thus, unless there is some reason to think that the agreements offer offsetting benefits to competition, they can be quickly condemned.

In sum, logic, economic theory, and record evidence demonstrate that the challenged agreements give rise to an intuitively obvious inference of anticompetitive effects. Established legal principles confirm that conclusion. Each agreement on its face contains a promise not to compete for some period of time. In purpose and effect, each agreement is a temporal market allocation, reserving sales of K-Dur 20 to Schering for several years, and requiring Upsher-Smith and AHP to refrain from selling their generic versions of K-Dur 20 during that time. As such, each constitutes a horizontal market allocation agreement. As Professor Hovenkamp has noted:

> [h]orizontal market division agreements come in a variety of forms. They may require participants to refrain (1) from producing one another's products, (2) from selling in one another's territories, (3) from soliciting or selling to one another's

> customers, or (4) from expanding into a market in which another participant is an actual or potential rival.[57]

Agreements not to compete are particularly suspect under the antitrust laws, because they "always or almost always tend to restrict competition and decrease output."[58] Horizontal market allocation agreements, the Supreme Court observed in *Palmer v. BRG of Georgia*, 498 U.S. 46 (1990) (per curiam), have consistently been found to be *per se* illegal because of their inherent anticompetitive character.

Palmer also made clear that market allocation agreements among potential competitors are as unlawful as those between firms that are current competitors at the time the agreement is entered into. As the cases discussed below demonstrate, the law does not require either actual competition among the parties to the agreement or certain entry in order to find an agreement not to compete. 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 wish to have "insurance" against such entry. As *Palmer* reflects, however, "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition."[59]

Two district courts have held that agreements involving generic drug potential entrants similar to those challenged here -- where an alleged infringer agreed to stay off the market for some period of time in exchange for a payment from the patent holder -- were, in economic

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[57] H. Hovenkamp, XII *Antitrust Law* ¶ 2030a at 172 (1999).

[58] *N.W. Wholesale Stationers, Inc. v. Pac. Stationery & Printing Co.*, 472 U.S. 284, 289-90 (1985).

[59] H. Hovenkamp, XII *Antitrust Law* ¶ 2030b at 175 (1999).

substance, horizontal market allocation agreements and *per se* illegal under the antitrust laws. In *In re Cardizem CD Antitrust Litigation*, 105 F. Supp.2d 682, 701 (E.D. Mich. 2000), *appeal docketed*, No. 00-2483 (6th Cir. Dec. 19, 2000), the court held that an agreement between HMRI, the brand name manufacturer, and Andrx, the generic entrant, 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."[60] Andrx received at least $40 million per year for, among other things, a promise not to market its generic product until it received a final unappealable judgment in the patent infringement case, and not to relinquish its 180-day exclusivity. The court rejected the argument that the agreement was not horizontal because HMRI and Andrx were not actual competitors, holding it was sufficient, to establish a horizontal market allocation agreement, that the parties were potential rivals, and that potential rivalry was eliminated. *Id.* at 700. The court also rejected the claim that the companies could not be potential competitors because the generic had no right to compete until the patent claims were resolved, or that the agreement had no actual effects because Andrx could have made a unilateral decision to stay off the market until conclusion of the patent litigation. *Id.* at 700-01.

Likewise, in *In re Terazosin Hydrochloride Antitrust Litigation*, 164 F.Supp.2d 1340, 1349 (S.D. Fla. 2000), *appeal pending*, the court found that a similar arrangement was a classic example of a *per se* violation in the form of "an agreement between competitors at the same level

[60] The D.C. Circuit in *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 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."

of the market structure to allocate territories in order to minimize competition."[61] The court rejected the claim that the agreements could not restrain competition because the generics would not have been in a position to enter the market any earlier than was permitted under the agreements. *Id.* at 1349. It also rejected a claim that patent settlements are not subject to the *per se* treatment, noting that the Supreme Court has condemned patent settlement agreements *per se*. *Id.* at 1352.

Because the "great likelihood of anticompetitive effects" from settlement agreements in this case "can easily be ascertained,"[62] the agreements can be summarily condemned unless respondents offer a plausible procompetitive justification.

B. Justifications Offered By Respondents Are Neither Sound in Theory Nor Supported by Evidence

Once plaintiffs make a prima facie showing that an agreement is anticompetitive, it is defendant's burden to come forward with a plausible procompetitive justification.[63] Justifications for anticompetitive conduct are cognizable under the antitrust laws only if they are based on a claim that the restriction enhances competition. The challenged practice may enhance

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[61] Two separate agreements were at issue in that matter. Geneva, the ANDA first filer, received $4.5 million per month for its agreement not to market its product until after it obtained a final, unappealable judgment that its product did not infringe Abbott's patents or until after another drug manufacturer marketed a generic product, and not to transfer rights to its generic products to another company. Zenith, a subsequent ANDA filer, accepted $3 million up front and $6 million per quarter to dismiss its legal challenge to Abbott's' having listed two patents with the FDA and thus subjecting Zenith to the 30-month Hatch-Waxman stay, and not to market its generic product until (1) another generic product was on the market, (2) Abbott allowed Zenith to enter, or (3) the patents expired. Zenith also agreed not to assist anyone else in developing a generic product. 164 F.Supp.2d at 1345-47.

[62] *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999) [hereinafter *CDA*].

[63] *Id.* at 769-70, *quoting NCAA*, 468 U.S. at 110.

competition by, for example, reducing the cost of producing or marketing a product, enabling the competitors to offer a new product, or improving the functioning of the market. Justifications that rest on the premise that competition is not in the public interest in the particular circumstances are not cognizable.[64]

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.[65] Courts reject proffered justifications that are that are pretextual;[66] that are not logically connected to achievement of the purported goal;[67] and that do not achieve or are not necessary to achieve their purported goals.[68]

In this case, the justifications that respondents offer for the challenged agreements should be rejected because they are pretextual -- that is, they are not supported by the evidence, or consist mainly of post-hoc rationalizations. To begin with, respondents' principal defense – that the payment to Upsher-Smith was for the licenses – is not supported by the evidence. Moreover, respondents' claim that the agreements were procompetitive because they permitted generic entry prior to expiration of the patent can be summarily rejected. Not only did the payments here lead

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[64] *See, e.g., NCAA*, 468 U.S. at 104; *Nat'l Soc'y of Prof. Eng's v. United States*, 435 U.S. 679, 696 (1978).

[65] P. Areeda, VII *Antitrust Law* ¶ 1505 at 384 (1986).

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

[67] *CDA*, 526 U.S. at 770-71, *citing Chicago. Prof. Sports LP v. NBA*, 961 F.2d 667, 674-76 (7th Cir. 1992) (quick look adequate after "assessing and rejecting logic of proffered procompetitive justifications").

[68] *See, e.g., Chicago Prof. Sports LP*, 961 F.2d at 674.

to later entry than otherwise would be expected absent the payments, but the suggestion that Schering would pay Upsher-Smith $60 million and AHP at least $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.

The fact that the agreements arise in the context of settlement of patent litigation does not, as respondents suggest, make *per se* condemnation inappropriate. The Supreme Court has previously held anticompetitive agreements settling patent disputes to be *per se* unlawful. *See United States v. Masonite Corp.*, 316 U.S. 265 (1942) (condemning settlement agreements between patent holder and alleged infringers, where patents assumed to be valid and infringed). Although respondents have also argued that the agreements are procompetitive because they conserved resources by ending litigation, they cannot demonstrate that settlements with payments to compensate an alleged infringer for refraining from competition are reasonably necessary to obtain the procompetitive benefits of settlements. This case does not challenge the settlement of patent disputes by an agreement on a date of entry, standing alone, or the payment of fair market value in connection with "side deals" to such an agreement. Rather, our challenge is to a substantial payment by the patent holder to the alleged infringer in consideration of a settlement agreement with delayed entry.

Finally, a number of economic experts retained by respondents have submitted reports that posit post-hoc "plausible circumstances" in which a payment for a future entry date might not result in delayed entry. But respondents point to no significant evidence that these theories are relevant to the specific circumstances in this case. The asserted reasons are implausible, or

are inconsistent with the available evidence. These speculations are merely that, and had nothing to do with the factors that actually motivated the agreements that were reached in this case. These theories, then, are not connected to the actual circumstances presented here, and in the end should have no bearing on this case.

Moreover, if the scenarios hypothesized in the expert reports were realistic, then one would expect that litigants would find it difficult to settle in the absence of payments, and that agreements in which payments were made to the purported wrongdoer would be widespread. In fact, the evidence will show that reverse payments from the plaintiff to the defendant are unheard of except in cases involving generic drug entry, where monopoly returns can be shared in a way that makes it worthwhile for the generic to delay entry.

In the absence of plausible justifications, the agreements can be condemned as *per se* illegal. And even if *per se* treatment is not indicated, the Supreme Court made clear in *NCAA* that inherently anticompetitive restraints can be condemned under the rule of reason if, upon examination, the offered justifications are found to be inadequate.[69] Under these standards, the agreements can be summarily condemned.

C. The Agreements Clearly Are Highly Likely To Harm Market-Wide Competition And Are Unlawful Under a More Searching Rule of Reason Inquiry

Even if a more searching examination of market power and the likely competitive effects of the agreements under the rule of reason is warranted, they still are unlawful. The purpose of looking at market power is "to determine whether an arrangement has the potential for genuine adverse effects on competition." *Ind. Fed'n of Dentists*, 476 U.S. 447 (1986). The central

[69] *See NCAA*, 468 U.S. at 100-01..

question in analyzing the agreements in this matter under the rule of reason is whether an agreement to delay generic competition to K-Dur 20 is capable of harming competition as a whole, as opposed to merely competition between the parties. In other words, would the exclusion of generic competition to K-Dur 20 force consumers to pay higher prices than they would if a generic version were available? Or, on the other hand, would the availability of other potassium chloride products prevent such an agreement from causing competitive harm?

Schering's agreements with Upsher-Smith and AHP are unlawful because Schering's position in the market and the competitive dynamic between branded pharmaceuticals and their generic versions show that the agreements plainly had the capacity to cause serious competitive harm. As was discussed at the outset of this brief, generic drugs present a unique kind of competition to their branded counterparts. The forecasts by Schering, Upsher-Smith, and AHP all show that these market participants believed that delaying generic entry would allow Schering to maintain high prices for K-Dur 20 without losing sales. And the direct evidence of the effect of generic entry on sales of K-Dur-20 since Upsher-Smith entered with its generic product in September 2001 leaves no doubt that the exclusion of generic competition caused consumers to pay higher prices for 20 mEq potassium chloride products

Thus, paying a competitor to refrain from competing is plainly anticompetitive, and Schering clearly had the power to harm consumers through such an agreement. Absent an efficiency justification, that is all that is needed to show harm to competition under the rule of reason. There is no need to show that Upsher-Smith or AHP would in fact have entered the market but for the settlements, or when such entry would have occurred. Uncertainty about whether such actual anticompetitive effects will occur, or even subsequent events that may make

the challenged conduct ineffective or unnecessary, do not undermine the anticompetitive nature of conduct that, at the time it was entered into, was likely to cause competitive harm.

Three recent decisions illustrate these principles. In *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001) (per curiam), the Court of Appeals for the D.C. Circuit held that the plaintiff in a monopolization case need not present direct proof that the defendant's continued monopoly power is precisely attributable to its anticompetitive conduct. 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 anticompetitive conduct that 'reasonably appear[s] capable of making a significant contribution to . . . maintaining monopoly power.'" 253 F.3d at 79, *quoting* Areeda & Hovenkamp, III *Antitrust Law* ¶ 651c at 69 (1996). It 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." 253 F.3d at 79 (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 threat is the type of conduct that is reasonably capable of contributing significantly to the defendants's continued monopoly power" and whether the potential entrants constituted nascent

threats at the time the conduct was undertaken. 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, companies at will . . . ." 253 F.3d at 79.

A decision of the D.C. Circuit in *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001), a case arising in the pharmaceutical industry, reflects the same principle. The case considered the agreement between HRMI and Andrx (that was held to be *per se* illegal in the *Cardizem CD* litigation discussed above) in the context of a claim by Biovail, a subsequent ANDA filer for generic Cardizem CD, that the HRMI/Andrx agreement unlawfully blocked its entry into the market. The District Court rejected Biovail's claim on the pleadings, based on its conclusion that Biovail had not, and could not, establish antitrust injury causally related to the HMRI/Andrx agreement, because its product had not yet received FDA approval and there was no assurance that it would enter the market if approval were granted. 256 F.3d at 806. The Court of Appeals reversed, holding that, in a suit for equitable relief, Biovail need only show a threatened injury. Although Biovail's product had not received the necessary FDA approval at the time the action was filed, the appellate court ruled that Biovail could adequately allege threatened injury by pleading facts sufficient to indicate its intention and preparedness to enter the market, and that FDA approval was probable. *Id.* at 806-08.

The court also rejected the theory that Biovail could not show that any injury to it flowed from the agreement, rather than from Andrx's unilateral decision to stay off the market and thereby avoid triggering the Hatch-Waxman exclusivity period. The court noted that the plaintiff need only show that the illegal conduct is a material cause of the injury; it need not eliminate all other possible sources of injury. *Id.* at 808. And, the court held, the facts alleged would support

a finding that the delay was attributable to the agreement. "A reasonable juror could conclude that Andrx's argument contradicts the very premise of the HRMI-Andrx agreement. . . . One can fairly infer . . . that but for the agreement, Andrx would have entered the market." *Id.* at 809. The court noted that HMRI's ten million dollar quarterly payments were presumably in return for something that Andrx would not otherwise do, that is, delay marketing of its generic. "Andrx's argument that any rational actor would wait for resolution of the patent infringement suit is belied by the *quid* of HMRI's *quo*." *Id.* at 813.

Microbix Biosystems, Inc. v. BioWhittaker, Inc., No. MJG-97-2525, 2000 WL 33405473 (D. Md. Mar. 28, 2000), *aff'd on other grounds*, No. 00-2262, 2001 WL 603416 (4th Cir. Jun. 4, 2001), arose out of a brand name manufacturer's entry into an exclusive supply arrangement with BioWhittaker, the only approved manufacturer of an essential raw material for the product, thereby denying a generic would-be entrant access to a necessary material. Subsequently, an FDA investigation of BioWhittaker led the agency to prohibit the use of the firm's material. The court denied summary judgment to the defendant on the generic drug maker's Section 1 claim, holding that even though subsequent events had made Microbix's entry into the market impossible, the exclusive supply agreement could still be condemned under the rule of reason, assuming it created a significant barrier to competition at the time it was entered into. *Microbix*, 2000WL 33405473 at *6. The court specifically rejected the argument that the anticompetitive effects of the agreement were minimal because of other factors that also prevented the plaintiff from successfully entering the market, emphasizing that the anticompetitive nature of the conduct was determined at the time it occurred. While subsequent events that prevented Microbix's entry into the market may be relevant to causation inquiries relating to damages, the court held these

factors "are not pertinent in assessing the effects of the alleged anti-competitive conduct on the market." *Microbix*, 2000 WL 33405473 at *9.

These cases demonstrate that establishing who would have won the infringement actions, and whether or when Upsher-Smith or AHP would have entered the market but for the agreements (or quantifying the possibility of those occurrences), is not an element of establishing that the agreements violate the Sherman Act under the rule of reason. *Microsoft* demonstrates that actions reasonably capable of preventing the emergence of competition to a monopoly are anticompetitive, even if the potential competition might have been unable to develop successfully in any event. *Andrx v. Biovail* confirms that it is proper to infer – from the fact of the substantial payments made to Upsher-Smith and AHP to secure their agreement to an entry date -- that there was a significant possibility that the generic companies would win the patent suits and enter the market. *Microbix* shows that the possibility that Upsher-Smith and AHP might have lost the patent suits, and in the end been unable to enter the market prior to expiration of the patents, does not eliminate the anticompetitive effect of the payments for the agreements that eliminated the risk of earlier entry by establishing an entry date. It is a sufficient demonstration of anticompetitive effects in this case that the settlement agreements, at the time they were entered into, appeared reasonably capable of significantly restricting competition from Upsher-Smith and AHP.

D. Showing That The Agreements Are Anticompetitive Does Not Require Inquiry Into The Likely Outcome of the Patent Infringement Litigation

We anticipate that one of respondents' principal arguments at trial will be that complaint counsel cannot establish that the challenged agreements are anticompetitive, absent proof of the likely outcome of the patent suits or the so-called "objective" probabilities that Upsher-Smith

and AHP would have won. While it is not clear precisely how respondents will articulate the burden they assert that complaint counsel bears, it is clear that antitrust laws do not require any such inquiry. Moreover, the impossibility of reliably conducting the inquiry that respondents contend is required confirms that assessing the anticompetitive effects of the challenged agreement without regard to an after-the-fact attempt to weigh the merits of the patent suits dispute is well-grounded both in law and sound antitrust policy.

1. The Courts Have Condemned Patent Settlements Without Assessing the Patent Issues

The courts have found patent settlements unlawful without an inquiry into patent invalidity or non-infringement. For example, in *United States v. Masonite Corp.*, 316 U.S. 265 (1942), the Court expressly assumed the patents in question were valid and infringed, but condemned the challenged agreements between the patent holder and alleged infringer. The case involved arrangements whereby competing manufacturers of wallboard entered into agreements with Masonite settling its claims that their products infringed its patents, withdrew their products from the market, and distributed Masonite's products, at prices set by Masonite. The district court found that the manufacturers had tried to design around Masonite's patents and had not been able to do so, and the Supreme Court therefore assumed Masonite's patents were valid and infringed. Nonetheless, the Court held that the arrangement between the patent holder and the alleged infringers was illegal, because it created "a powerful inducement to abandon competition." *Id.* at 281. *See also United States v. Singer Mfg Co.*, 374 U.S. 174 (1963) (condemning agreements among competitors settling a patent interference proceeding that served to avoid possible invalidation of their respective patents); *United States v. New Wrinkle, Co.*, 342 U.S. 371 (1952), (condemning licensing agreement that settled a patent interference

proceeding without resolving patent dispute); *United States v. Line Materials Co.*, 333 U.S. 287 (1948) (licensing agreement found to violate the Sherman Act without a determination of patent invalidity or non-infringement).

As these cases demonstrate, patent holders – regardless of the merits of their patent infringement contentions – may not induce competitors to abandon competition with their own products through an arrangement to share monopoly profits. That principle is sound, whether the sharing of profits is achieved through a price-fixing agreement or, as in this case, a market allocation agreement. Such agreements not to compete are economically equivalent.[70]

More recent decisions addressing antitrust challenges to settlement agreements arising in a Hatch-Waxman context have directly and soundly dismissed arguments that patent law or antitrust law requires the plaintiff to establish the likely outcome of the underlying patent case. Both the *Cardizem CD* and *Terazosin Hydrochloride* cases, discussed above, squarely rejected such arguments.[71] And more recently, another case, based on allegations of payments not to compete similar to the charges here, reached the same conclusion. *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 166 F. Supp. 2d 740 (E.D. N.Y. 2001), involved charges that Bayer Corporation, the patent holder, paid over $100 million to a potential generic entrant to settle its patent infringement suit. The court addressed the question whether the plaintiffs' challenge would necessarily depend on questions of patent law. The court ruled that the

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[70] *See, e.g., General Leaseways, Inc, v. Nat. Truck Leasing Ass'n*, 744 F.2d 588, 594-95 (7th Cir. 1984) (raising price, reducing output, and dividing markets have the same anticompetitive effects).

[71] *In re Cardizem CD Antitrust Litig.*, 105 F. Supp.2d at 700; *In re Terazocin Hydrochloride Antitrust Litig.*, 164 F.Supp.2d at 1352.

plaintiffs had alleged a theory of liability that did not depend on a showing of patent invalidity – that absent the settlement agreement sharing profits with the potential generic entrant, Bayer would have permitted generic entry rather than risk a possible finding of patent invalidity. *Id.* at 748. In so doing, the court directly rejected the argument that the existence of a valid patent forecloses the possibility of antitrust effects flowing from the agreement. *Id.* at 749. The court also dismissed the assertion that showing non-infringement was essential to establishing liability because consumers have no right to purchase a non-infringing product. The crux of the case, the court noted, was not a claimed right to buy infringing products, but rather the "right to a market in which manufacturers and distributors of generic drugs make their decision about challenging patents and entering markets free from the influence of cash payments amounting to unreasonable restraints of trade." *Id.*

Respondents apparently intend to rely on a section of a treatise written by Professor Hovenkamp as the legal foundation for their argument that complaint counsel must prove the merits of the patent case.[72] Relying on Hovenkamp's analysis for considering whether a settlement is a reasonable accommodation of a bona fide dispute, Upsher-Smith argues that a settlement is clearly lawful so long as entry under the agreement occurs earlier than the expiration of the patent (because a win by the patent-holder is one possible outcome of the litigation). Schering makes a different argument based on the same passage in the treatise: that to establish that a settlement agreement is anticompetitive, it must be shown that the split of the

[72] *See* H. Hovenamp, XII *Antitrust Law* ¶ 2056 at 267. Respondents relied extensively on Professor Hovenkamp's analysis in their motions to dismiss the complaint. In addition, several of respondent's expert witnesses rely on the discussion in the treatise.

patent life does not correspond to the parties' "objective" chances of prevailing in the patent case, as Schering asserts. Both arguments are misplaced.

To begin with, Hovenkamp's discussion plainly does not address the kind of agreements at issue here. His analysis assumes the settlement is a reasonable compromise of the parties' respective positions, unlike here where a "reverse payment" to the alleged infringer distorts the defendant's incentives concerning settlement. Indeed, in the horizontal restraints section of the 2001 Supplement to the Areeda & Hovenkamp treatise, he discusses with apparent approval the decision in *In re Cardizem CD Antitrust Litigation* that the agreement involving payments to the alleged infringer in a patent infringement case was *per se* unlawful.[73]

Professor Hovenkamp's more recent comments are not surprising, because neither his earlier analysis nor the cases he cites supports respondents' contention. What Hovenkamp says is that in cases involving "reasonable accommodation" of a bona fide dispute, analysis under the rule of reason, including an inquiry into power and anticompetitive effects, is usually called for.[74] The cases that he cites for that conclusion involve an inquiry into the effect of the restriction on market-wide competition. That is different from a comparison of the challenged conduct and the likely or possible outcome of the litigation.[75] The most that Professor Hovencamp's analysis

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[73] H. Hovenkamp, *Antitrust Law* 2001 Supplement at ¶ 1509.

[74] H. Hovenkamp. XII *Antitrust Law* ¶ 2056 at 267 (1999).

[75] *See Standard Oil Co. (Ind.) v. United States*, 283 U.S. 163 (1931) (agreement settling patent infringement and interference proceedings relating to a particular method of refining gasoline with cross-licensing and royalty-sharing arrangement found to be lawful because it did not restrict competition in the market for gasoline); *Clorox Co. v. Sterling Winthrop, Inc.*, 117 F.3d 50 (2d Cir. 1997) (settlement of trademark infringement litigation lawful because it did not restrain competition in the disinfectant cleaner markets in question).

suggests is that an antitrust court reviewing a settlement agreement -- that otherwise appears to be a reasonable accommodation of a bona fide dispute -- needs to look at whether the settlement had an impact beyond just competition among the parties.

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. Moreover, such an assessment is not needed to show the requisite causal link between the agreement and competitive harm. As was discussed above, in an injunction action the existence of uncertainty as to a potential competitor's ultimate entry into the market does not preclude a showing of competitive harm.

2. The Inquiry That Respondents Urge Is Neither Feasible Nor Reliable

Although respondents claim that the tens of millions of dollars in non-contingent payments that Schering made to Upsher-Smith and AHP were not consideration for the agreed-upon entry dates, they have proffered numerous expert witnesses in an effort to make a further argument. In essence, they argue that, even if it is shown that Schering's payments were to secure the generic firms' agreement to entry dates several years in the future, such payments not to compete could serve useful purposes and might not in fact delay entry. Accordingly, respondents have made various arguments regarding the need to inquire into the relative merits of the parties' patent claims. Sometimes they have argued that we need to prove that the Upsher-Smith and AHP products did not infringe Schering's patent, or suggested that we must prove the likely outcome of the patent case. Other times they have contended that we must prove the

"objective" probability of the parties prevailing in the infringement suits and compare that to the parties' determination of when competitive entry would be permitted.

None of these tests is possible to carry out in a meaningful way. We will never know who would have won the patent cases. Respondents, through their challenged agreements, withdrew the matters from the courts. And there is no way to go back and recreate the conditions of the original law suits. The potential entrant no longer has the same incentive to defend its product against the claim of infringement. Plainly, we can never know how those judges and juries would have decided the cases.

Still less can we quantify each party's chance of success. There simply is no known methodology for handicapping trials or for testing the reliability of predictions. Indeed, Respondents intend to offer the testimony of a number of expert witnesses who will explain why the outcome of patent litigation cannot reliably be predicted. James P. O'Shaughnessy, for example, a patent trial lawyer and one of Schering's expert witnesses, stresses that [redacted] and that in the cases in which he has been involved, he frequently has been

> [redacted]

For this reason, Mr. O'Shaughnessy states,

> [redacted] [76]

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[76] O'Shaughnessy Expert Report at 4, 6, 9.

Dr. William O. Kerr, one of Upsher-Smith's economic experts, makes a similar point:

> ********** [77]

And most remarkably, respondents assert that such an assessment is essential while hiding behind the attorney-client privilege to shield their own contemporaneous assessments from examination.

The analysis that we will present during the trial is firmly based on established economic principles and methods. The task that respondents' experts urge on this court, by contrast, is not based on established or testable principles and methods, and is not reliable. Although respondents insist what is needed is an "objective" assessment of the probabilities in the patent case, what they actually appear to call for is a subjective retrospective evaluation of the evidence and arguments assembled in the patent case, by a third party or by this court, based on his or her own opinions and estimates. 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. What respondents are offering -- in the form of experts on patent issues who seek to opine on the merits of the parties' patent cases -- are merely subjective opinions based on a very limited universe of information. For example, respondents have refused to produce a great deal of information about their perceptions of the likely outcome of the patent cases and about the negotiation of the agreements, pursuant to claims of attorney client and work product privilege. This information presumably is not

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[77] Kerr Expert Report at 20.

available to respondents' experts, and it certainly is not available for use on cross-examination to test the basis and validity of the expert testimony. In short, there is no satisfactory way to test the reliability of these assessments of the likely or possible outcomes of the patent cases. While complaint counsel intend to offer rebuttal witnesses if these patent experts testify, we do so merely to show that Upsher-Smith and AHP each had a reasonable possibility of winning the suits, and thus posed real threats to Schering's monopoly power at the time of the settlement agreements.

Respondent's experts assert that the competitive effect 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. Each proposes a test for assessing the competitive impact of payments in consideration of settlement agreements, but the tests are inconsistent, and none can be implemented satisfactorily. Indeed, the Respondents apparently do not intend to offer any witnesses who will even attempt to apply any of these tests to the facts of this case, or to quantify any party's chance of prevailing in the lawsuits.

For example, Schering's expert, Dr. Robert Willig, discusses a number of complicated hypothetical situations in which parties might reach a settlement agreement that contained a net payment to the generic potential entrant that would not be anticompetitive (in the sense that it would contain an entry date that was consistent with the "probable" outcome of the litigation). These factors include the cost of bearing risk, concern about the entrant's ability to pay damages if it entered prior to final determination of the patent case and later was held liable for infringement, different discount rates, information asymmetries relating to factors such as the economic life of the patent, and the effect on the generic company's earnings of possible entry of

subsequent generic products. Nothing in the available evidence points to any of these factors as a reason for the payments to Upsher-Smith and AHP. Nonetheless, on this basis, Dr. Willig claims that a determination of the anticompetitive nature of agreements requires consideration of all the evidence, including [redacted][78] as well as other factors, including the character of the agreement, its commercial setting, and the business needs of the parties.[79] Such an open-ended and standardless test would neither offer a reliable guide in adjudication nor provide guidance to businessmen in the settlement of future cases. Moreover, Dr. Willig makes no effort to analyze the agreement under this standard.

Upsher-Smith's expert, Dr. Ordover, in contrast, argues that there is no one precise entry date that can be deemed reasonable or legitimate.[80] Indeed, at his deposition he testified that it was likely beyond the capabilities of the legal system to attempt to determine, with any degree of precision, the probable date of entry under litigation.[81] Instead, he would seek to determine a range of [redacted] entry dates to which the date agreed upon in the settlement would be compared.[82] This range of entry dates would be based on the evidence available in the litigation and the parties' [redacted][83] In his deposition,

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[78] Willig Expert Report at 3.

[79] Willig Deposition at 16:15 - 19:11 and 35:12 - 36.6.

[80] Ordover Expert Report at 8, ¶ 17.

[81] *See, e.g.*, Ordover Deposition at 91:11 - 24, 93:5 - 94:1.

[82] Ordover Expert Report at 8, ¶ 17.

[83] *Id.* at 9, ¶ 19.

however, Dr. Ordover conceded that in order to implement his proposed test, it was necessary to know the parties' own contemporaneous assessments of the odds of their prevailing in the litigation.[84] Thus, to implement his test a court would either have to compel disclosure of privileged attorney-client information, or draw adverse inferences from the parties' failure to produce that information. Indeed, Dr. Ordover's test suggests that, since Upsher-Smith has steadfastly refused to provide the information that its own expert says is essential to determine the legality of the settlement agreements, that adverse inferences should be drawn in this case. And of course, there is a risk that in future cases, parties anticipating possible antitrust scrutiny, as Schering did for the agreements challenged here, could simply generate documents tailored to the test that Dr. Ordover proposes.

Both Dr. Willig and Dr. Ordover concede that settlements like the one challenged here *could* harm competition. As we will show, consideration of the agreements challenged in this case, in the specific context out of which they arose, will show that the payments were for the assurance of delayed entry, and did not grow out of the factors about which respondents' experts speculate. Indeed, Dr. Ordover expresses a number of opinions that support the conclusion that the agreements in this case were in fact anticompetitive. For example, he agrees with complaint counsel: (1) that it is critical to rely on the parties' contemporaneous assessment of their chances in the litigation and the reasons the parties structured the arrangement as they did, rather than "ex post rationalizations;"[85] (2) if the amount of the payment were closely related to the profit that the generic would have earned during the period between the settlement and when it was permitted

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[84] *See, e.g.*, Ordover Deposition at 49:5 - 54:11.

[85] *Id.* at 52:7-8, 49:5 - 54:11.

on the market -- as is the case here -- that would be cause for further inquiry into the basis for the payment;[86] (3) evidence that [redacted] or that [redacted] would support a conclusion that the entry date would have been earlier but for the payment;[87] and (4) in the absence of a precise determination as to the expected litigation outcome, a fact finder could reasonably select the earliest possible date of entry (based on the range of entry dates corresponding to the parties' assessment of the likely outcome of the litigation) as the benchmark against to which to compare the entry date in the settlement agreement.[88]

While respondents' own experts concede that settlements with payments to the alleged infringer can be anticompetitive, by advocating tests that are impossible to apply they adopt a rule that would effectively immunize such settlements. Given the undeniable incentives for branded drug manufacturers and potential generic entrants to reach patent settlements that involve payments for delay, consumers are far better served by an analysis that places the burden on defendants to show that a reverse payment was not for delay, than one that would permit reverse payments for such settlements as a matter of course. 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.

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[86] *Id.* at 49:5-50:7.

[87] Ordover Expert Report at 21, ¶ 44.

[88] Ordover Deposition at 148:17 - 149:20.

VI. The Agreements Constitute Monopoly Maintenance and Conspiracies to Monopolize

Because the challenged agreements in this case were designed to delay entry of generic versions of K-Dur into the market and thus to extend Schering's monopoly power, the agreements also constitute monopoly maintenance by Schering and were in furtherance of a conspiracy by Schering and Upsher-Smith, and Schering and AHP, to monopolize.

A. Schering Had Monopoly Power

Schering has monopoly power with respect to K-Dur 20 -- that is, "the power to raise price above cost without losing so many sales as to make the price rise unsustainable."[89] 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.[90] The purpose of defining a relevant antitrust product market is to identify which products constrain the exercise of market power. The functional interchangeability between products provides only "the outer boundaries of a product market."[91] When products, like pharmaceuticals, can be used for the same purpose but differ significantly in terms of price, quality, consumer preferences, or other significant attributes, the products are differentiated. While differentiated products

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[89] *In Re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 603 (7th Cir. 1997) (Posner, J.), *cert. denied*, 118 S.Ct 1178 (1998) (noting that patented pharmaceuticals may be close but not perfect substitutes, so that the seller of each product has some monopoly power).

[90] *See, e.g., United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (per curiam); *ReMax Int'l. Inc. v. Realty One, Inc.*, 173 F.3d 995, 1016 (6th Cir. 1999).

[91] *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962).

compete at some level, 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."[92]

The evidence amply shows that Schering possessed monopoly power. The courts and the Commission have 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.[93] In *Smith Kline Corp. v. Eli Lilly Co.*, 575 F.2d 1056 (3d. Cir. 1978), for example, the court of appeals upheld a finding by the district court that cephalosporin antibiotics constituted a separate market from other anti-infective agents, even though those agents were used to treat many of the same conditions as were cephalosporins, because the amounts of cephalosporins and non-cephalosporin agents purchased were not related to the relative prices of those products. *Id.* at 1063-64. Likewise, in *Federal Trade Commission v. Staples, Inc.*, 970 F. Supp. 1066, 1077 (D.D.C. 1997), 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" *Id.* at 1075. The court found that evidence

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[92] *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1063 (3d. Cir. 1978), *cert. denied*, 439 U.S. 838 (1978).

[93] *See e.g., Coca-Cola Bottling Co. of the Southwest*, 118 F.T.C. 452, 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 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).

that the superstores charged significantly more in markets where there were no other superstores, than in markets where one or two other superstores operated, among other evidence, established a low cross-elasticity of demand between the superstores and other office supplies sellers, and thus the existence of a separate superstore market. *Id.* at 1078.

There is ample evidence to show that Schering's pricing of K-Dur 20 was not effectively constrained by the availability of other potassium chloride supplements. As complaint counsel's economic expert, Professor Bresnahan, will explain at trial,[94] Schering's monopoly power is shown by evidence that:

- sales of K-Dur 20 have continued to grow relative to lower-priced potassium chloride supplements even in the face of price increases;
- Schering, Upsher-Smith, and AHP all forecast increasing K-Dur sales and profits so long as Schering could keep generics out of the market, and sharply reduced sales with lower overall consumer prices once generic entry occurred;
- consumers and physicians do not regard other potassium chloride supplements as close substitutes for K-Dur 20;
- K-Dur 20 has clear therapeutic advantages over other supplements, and a unique dosage strength;
- empirical research on the pharmaceutical industry shows the unique effect of generic entry on sales of branded drugs, in particular that sales of the generic drug come almost entirely at the expense of the branded counterpart, and have little or no impact on sales of other products, even those used for the same therapeutic purpose;
- when Upsher-Smith finally entered with its lower-priced generic K-Dur 20 product in September, 2001, Schering's sales suffered a rapid and dramatic decline, losing nearly 70 percent of new prescriptions for 20 mEq potassium chloride supplements.

Since other potassium chloride products did not constrain Schering's pricing, 20mEq potassium chloride products is a relevant market for purposes of evaluating the effect of

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[94] *See* Bresnahan Expert Report at 23-26.

excluding generic versions of K-Dur 20. Schering's monopoly power in that market, prior to the introduction of generic K-Dur 20, is clear.

B. Monopoly Maintenance

The offense of monopolization condemned by Section 2 of the Sherman Act has two elements: (1) the possession of monopoly power; and (2) the willful acquisition or maintenance of that power through exclusionary conduct.[95] Thus, when a monopolist uses its power to foreclose competition, it violates Section 2, for "[t]he antitrust laws are as much violated by the prevention of competition as by its destruction."[96] 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).

As was discussed above, the evidence establishes that Schering had monopoly power. The evidence that we will offer to prove that the agreements unreasonably restrained horizontal competition satisfies the exclusionary conduct element of the test. The agreements were designed to delay generic competition to Schering's K-Dur 20. As the Court of Appeals for the D.C. Circuit held in *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (per curiam), a violation of Section 2 is established by a finding that the defendant engaged in anticompetitive conduct designed to exclude potential or nascent competition, without any need

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[95] *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

[96] *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).

to show that such potential competition would have successfully constrained the monopolist's power in the absence of the anticompetitive conduct. Thus, the evidence will show Schering's agreements with Upsher-Smith and AHP were acts of monopolization.

C. Conspiracy to Monopolize

The complaint also alleges that Schering and Upsher-Smith, and Schering and AHP, conspired to monopolize the relevant market. The elements of a conspiracy to monopolize are: 1) the existence of a combination or conspiracy, and 2) an overt act in furtherance of the conspiracy, and 3) specific intent to monopolize.[97]

The agreement element of the conspiracy to monopolize is satisfied by the written settlement agreements that Schering entered into with Upsher-Smith and AHP. The second element, an overt act in furtherance of the conspiracy, is met by Schering's payment of $60 million to Upsher-Smith and $15 million or more to AHP, the acceptance of those payment by Upsher-Smith and AHP, the voluntary dismissal of the patent litigations, and the delayed launch of Upsher-Smith's product after it received tentative FDA approval.

The third element, specific intent to monopolize, may be shown either by direct evidence of the defendant's state of mind, or by inference from the defendant's conduct.[98] Parties are presumed to intend the natural consequences of their actions. "[I]f the ordinary business conduct of a dominant firm leads to the acquisition or maintenance of monopoly power, that conduct is

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[97] *See, e.g., United States v. Yellow Cab.*, 332 U.S. 218, 225 (1947); *Volvo N. Am. Corp. v. Men's Int'l Prof'l Tennis Council*, 857 F.2d 55, 74 (2d Cir. 1988); *Kellogg Co., et al.*, 99 FTC 8, 263 (1982).

[98] *See Am. Tobacco Co. v. United States*, 328 U.S. 781, 809 (1946).

presumed to reflect the requisite willful monopolistic intent." *MCI Communications Corp. v. AT&T*, 708 F.2d 1081, 1108 (7th Cir. 1983).

Schering's statements and actions demonstrate its specific intent to maintain its monopoly of the K-Dur market, and Upsher-Smith's and AHP's actions show their intent to share with Schering the returns from doing so. Through the Upsher-Smith agreement, Schering delayed the possibility of competition from its generic product and, with the agreement with AHP, cemented Schering's control of the market until September 2001. Upsher-Smith's specific intent is evidenced by actions and statements, including its offer to Schering to stay off the market in return for compensation, that show an intent to preserve Schering's monopoly in exchange for a share of Schering's monopoly profits. Likewise, AHP's specific intent to suppress generic competition and share Schering's monopoly profits is demonstrated by its willingness to stay off the market until a later date as long as Schering paid AHP to do so, and its statements that it was entitled to payment from Schering to replace the revenues it was foregoing by not launching its competing product.

VII. Respondents Have No Noerr-Pennington Defense

In their answers to the complaint and motions to dismiss, Schering and Upsher-Smith have made various claims to antitrust immunity under the *Noerr-Pennington* doctrine, which protects competitors when they seek governmental action, even when they intend anticompetitive results. It is clear, however, that respondents have no *Noerr* immunity.

The *Noerr* doctrine protects petitioning for governmental action.[99] As the Court of Appeals for the D.C. Circuit recently observed in *Andrx Pharmaceuticals v. Biovail Corp. International*, 256 F.3d 799, 817-19 (D.C. Cir. 2001), settlement agreements among private litigants do not constitute petitioning or conduct "incidental" thereto, and are not *Noerr* protected.[100] And although Schering has suggested that its agreement with AHP might still be protected on the theory that the magistrate supervised or, even implicitly approved, the agreement, this claim does not advance its *Noerr* argument. The anticompetitive harm challenged here stems from the agreement between Schering and AHP, and not any act of government.

Furthermore, as we discussed in our opposition to respondents' motions to dismiss the complaint, equally unavailing is respondents' claim that the *Noerr* doctrine bars the charge that the agreement had exclusionary effects on other potential generic entrants, because that effect flows from the law rather than from the agreement. First, this argument has nothing to with petitioning government, and thus does not present any *Noerr* issue. Second, as various courts

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[99] *See, e.g., Prof. Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56 (1993) (*Noerr* immunity applies to those who petition the government); *MCI Communications Corp. v. AT & T*, 708 F.2d 1081, 1159 (7th Cir. 1983) ("The Noerr-Pennington doctrine is concerned solely with the right to attempt to influence government action.").

[100] The D.C. Circuit, considering the Hoechst/Andrx agreement, rejected the argument that a private settlement was incidental to litigation, and stated:

> The Agreement is not unlike a final, private settlement agreement resolving the patent infringement litigation by substituting a market allocation agreement. Such a settlement would not enjoy *Noerr-Pennington* immunity and neither does the Agreement here.

256 F.3d at 819.

have recognized, a branded drug maker's payment to the first ANDA filer to secure an agreement that serves to delay the triggering of the 180-day exclusivity period that the Hatch-Waxman confers on first generic applicants directly harms competition and consumers -- in a way that the statutory scheme does not.[101]

Respectfully submitted,

Karen Bokat / Cal Eisenstat

Karen G.. Bokat
Philip Eisenstat
Complaint Counsel

Dated: January 23, 2002

[101] *See Andrx Pharm. v. Biovail, Inc.*, 256 F.3 799, 808-810 (D.C. Cir. 2001) (reversing district court decision that any injury to Biovail (the second generic filer) could not be attributed to the agreement between first filer Andrx and Hoechst, given the delay period prescribed by Hatch-Waxman); *Biovail Corp. International v. Hoechst A.G.*, 49 F.Supp.2d 750, 768 (D. N.J. 1999) (rejecting defendants' argument that antitrust claim against the Hoechst/Andrx agreement was merely "frustration with the statutory exclusivity period" and finding that the complaint challenged an alleged "abuse of the statute."); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp.2d 618, 658, 663 (E.D. Mich. 2000) (Hatch-Waxman Amendments permit certain unilateral action but do not authorize agreements to restrain trade).

Table of Appendices

Appendix A

Appendix A: FTC Case in Chief Witnesses

Professor Timothy F. Bresnahan

Professor Bresnahan is a professor of Economics at Stanford University, where he has held that position 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.

In his testimony Professor Bresnahan will apply peer reviewed, published, and empirically validated economics which shows that generic entry threatens the branded drug monopolies, and that entrants and monopolists have the capability and the incentive to delay that entry. Flowing directly and naturally from this peer reviewed literature, Professor Bresnahan will testify that if [redacted]

[redacted]

[redacted]

[redacted] will testify about the use of potassium chloride to treat patients with abnormally low potassium levels and the differences among potassium chloride supplements. He will explain the process for selecting potassium chloride supplements for [redacted]'s formulary. He will also testify about the impact of generic entry in reducing drug prices and how generic drugs save money for patients and payors.

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 also teaches FDA regulatory law as an adjunct professor of law at two law schools, and has been an invited presenter at numerous

Continuing Legal Education programs on FDA regulatory law.

Mr. Hoffman will testify that in his expert opinion:

[redacted]

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.

Dr. Levy's testimony will address whether the $60 million non-contingent payment by Schering to Upsher was for the Niacor-SR product. Dr. Levy's expects to testify that [redacted]

[redacted]

[redacted] will testify that [redacted] submitted an ANDA for its generic of K-Dur 20 in 1999 and that [redacted] cannot obtain final approval from the FDA until Upsher's 180-day exclusivity expires. [redacted] will testify that [redacted] generic will compete directly with Schering's K-Dur 20 and Upsher's generic version of K-Dur 20, and that [redacted] generic will compete on price.

[redacted]

[redacted] will testify generally about [redacted]'s prescription drug coverage program, the cost-savings represented by generic drugs, and cost-containment strategies. In addition, [redacted] will testify about the use of potassium chloride in the treatment of patients with low potassium levels.

Appendix B

Appendix B: Identification of Individuals

	NAME	TITLE/POSITION
1.	**American Home Products Corporation (AHP)**	
	**********	**********
	**********	**********
2.	**********	
	**********	**********
3.	**Key Pharmaceuticals, Inc.** (Subsidiary of Schering-Plough Corporation responsible for K-Dur 20)	
	Dilascia, Chris	Former Senior Product Manager
	Driscoll, Martin	Former Vice President of Marketing & Sales for Primary Care
	Herman, Tony	Outside Patent Counsel to Key in Key/ESI Litigation
	Rule, Rick	Outside Antitrust Counsel to Key in Key/ESI Litigation
4.	**********	
	**********	**********
	**********	**********
5.	**Schering-Plough Corporation**	
	Audibert, James	Senior Director of Commercial Optimization
	Becherer, Hans W.	Member of Board of Directors
	Cesan, Raul	Former President & Chief Operating Officer
	DeMola, Antonia	Director of Field Information & Sales Force Strategy

NAME	TITLE/POSITION
Schering-Plough Corporation	
Garfield, David C.	Former Member of Board of Directors
Gast, Karin	Senior Director of Business Development
Genito, Anthony	Staff Vice President-Assistant Controller of Accounting Operations
Grewcock, David	Senior Director of Global Marketing
Hoffman, John	Staff Vice President & Associate General Counsel
Kapur, Raman	Head of Worldwide Generics Schering-Plough; President of Warrick Pharmaceuticals (Subsidiary of Schering that sells generic pharmaceuti products)
Kogan, Richard	Chairman & Chief Executive Officer
Lauda, Thomas	Executive Vice President of Global Marketing
Miller, Dr. Lawrence G.	Former Senior Director of Pharmaceutical Research
Morley, H. Barclay	Member of Board of Directors
Mundy, Carl E. Jr.	Member of Board of Directors
Poorvin, David	Vice President of Business Development
Russo, Patricia F.	Member of Board of Directors
Russo, Raymond	Senior Director of Marketing for Cardiovascular Products
Schreyer, William A.	Member of Board of Directors
Wasserstein, Jeffrey	President & General Manager, Schering-Plough Canada
Weintraub, Harvey	Consultant, Former Vice President of Marketing & Sales Support, Form Vice President of Warrick Pharmaceuticals

	NAME	TITLE/POSITION
6.	**Upsher-Smith Laboratories, Inc.**	
	Canella, Nicholas M.	Outside Patent Counsel to Upsher in Key/Upsher Litigation
	Coleman, Bob	Director of Marketing
	Dolan, Denise	Product Manager
	Dristsas, Phillip	Vice President of Sales & Marketing
	Freese, Lori	Professional Services Manager
	Gould, Scott	Purchasing Manager
	Halvorsen, Mark	Director of Clinical & Regulatory Affairs
	Hirschberg, Andrew	Consultant to Upsher during patent litigation with Key
	Kravolec, Paul	Chief Financial Officer & Vice President of Distribution
	O'Neill, Vickie	Vice President of Business Development & Project Management
	Robbins, Mark	Vice President of Scientific Affairs
	Troup, John A. (Ian)	President & Chief Operating Officer
	Valazza, Mike	Vice President of Business Department
	Woodruff, Chuck	Vice President of Operations
7.	**Other Witnesses**	
	.....	.....

Appendix C

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.

Appendix D

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6. CX 484: ••

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CERTIFICATE OF SERVICE

I, Andrew S. Ginsburg, hereby certify that on January 23, 2002:

I caused two copies of the public version of Complaint Counsel's Trial Brief to be served upon the following person by hand delivery-

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
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I caused one original and one copy of the public version of Complaint Counsel's Trial Brief to be served by hand delivery and one copy to be served by electronic mail upon the following person-

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