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

PUBLIC VERSION

COMPLAINT COUNSEL'S OPPOSITION TO UPSHER-SMITH'S MOTION TO DISMISS

March 4, 2002

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On a motion to dismiss for failure of proof at the close of the case-in-chief, the Court must decide only whether there is reliable record evidence to support the complaint. The Court's task is not to weigh the evidence or resolve factual disputes. Instead, the evidence and reasonable inferences to be drawn therefrom must be viewed in the light most favorable to the complaint.[1] Where there is evidence to support the complaint, the motion to dismiss must be denied.

The complaint in this case charges that Schering paid would-be generic rival Upsher-Smith $60 million to secure an agreement not to enter the market for over 4 years, and that this agreement constitutes an unlawful horizontal restraint, an act of monopolization, and a conspiracy to monopolize. Because it is an agreement between competitors or potential competitors that governs the way they compete with one another, it is a horizontal restraint of

[1] *See, e.g., Vulcanized Rubber and Plastics Co.*, 52 F.T.C. 533 (1955).

trade, and is unlawful if it unreasonably restrains competition.[2] Paying a competitor to stay off the market is plainly anticompetitive, has no plausible justification, and the agreement is therefore an unlawful horizontal restraint.[3] The agreement is an unlawful act of monopolization, because Schering had monopoly power with respect to K-Dur 20, and it maintained that power through exclusionary conduct.[4] And the agreement amounts to an unlawful conspiracy to monopolize, because 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.[5]

There is ample evidence to support the violations charged against Upsher-Smith. This evidence shows that Upsher-Smith entered into an agreement with Schering in which it was paid millions of dollars for a promise not to compete, that Schering had monopoly power, and that the parties entered into this agreement with the specific intent to extend Schering's monopoly power. This evidence is more than enough to support the complaint and requires denial of the motion to dismiss. As we discuss below, Upsher-Smith's numerous claims concerning the supposed failure

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

[3] *See Broadcast Music, Inc. v. CBS*, 441 U.S. 1 (1979).

[4] *See United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (per curium) (finding a violation of Section 2 where defendant engaged in anticompetitive conduct designed to exclude potential or nascent competition, without the need to show that such potential competition would have successfully constrained the monopolist's power in the absence of the anticompetitive conduct).

[5] *See, e.g., United States v. Yellow Cab*, 332 U.S. 218, 225 (1947).

of proof here rest on erroneous statements of what is required to establish the violations charged in the Commission's complaint.

I. The Prima Facie Case of a Payment Not to Compete

The Commission's challenge to Upsher-Smith's agreement with Schering rests on the fundamental factual premise that Schering paid Upsher-Smith in exchange for an agreement to stay off the market. There is no dispute that under the challenged agreement Schering paid Upsher-Smith $60 million, and Upsher-Smith agreed not to launch any competing product for over four years. What is disputed is whether the $60 million in non-contingent payments was, in whole or in part, consideration for Upsher-Smith's promise not to compete until 2001. The only alternative explanation respondents have offered for this enormous, unconditional cash payment is that it was additional consideration for the licenses to certain Upsher-Smith products, above and beyond the milestone and royalty payments specified in the agreement. Once it is shown that the $60 million could not have been simply payment for the licenses, the inescapable conclusion is that Schering paid Upsher-Smith to secure its agreement to stay off the market.

The most direct evidence of the nature of the agreement and the purpose of the $60 million payments – the parties' written agreement itself (CX 348) – on its face provides that Schering's payments were "consideration" for Upsher-Smith's agreement not to launch any generic version of K-Dur 20 until September 2001. Paragraph 11 expressly states that Schering's payments – including so-called "up-front royalty" payments of $60 million over two years – are

consideration for the entire set of obligations owed by Upsher-Smith in paragraphs 1-10, including the obligation to stay off the market until 2001.[6]

A variety of other evidence confirms that Schering's payments were not solely for the licenses it obtained from Upsher-Smith.[7] Although respondents have sought to explain away what appears on the face of the agreement and other contemporaneous documents, the evidence plainly makes a prima facie showing that Upsher-Smith's settlement agreement with Schering involved payments in return for a promise not to compete. It shows, for example that:

- Schering had a powerful incentive to pay Upsher-Smith to delay its entry. Schering expected generic entry as early as 1997 and well before its patent would expire in 2006.[8] And it was acutely aware of how quickly its K-Dur 20 profits would plummet once generic competition did arrive, making any delay in generic entry extremely valuable.[9]

- Upsher-Smith was well aware of the dramatic impact its entry would have on Schering's profits.[10]

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[6] CX 348 at USL 3188 ("In consideration for the licenses, rights and obligations described in paragraphs 1 through 10 above, SP licensee shall make the following payments to Upsher-Smith . . . .").

[7] A Schering official testified that the payment was almost entirely for Niacor-SR. CX 1510 (Kapur IH at 86).

[8] *See, e.g,* CX 13 at SP 003044 (1995 internal Schering memorandum noting that generic competition to K-Dur 20 may come within two years); CX 124 (assuming generic K-Dur 20 launch in 1997); CX 128 at SP 23 00325a (Key Five Year Sales Forecast assuming generic K-Dur 20 entry in July 1997); CX 18 at SP 23 00044 (1997 K-Dur Marketing Plan predicting generic entry in 1998); CX 121 at SP 23 00301a (internal forecast assuming generic K-Dur 20 entry in 2nd Quarter of 1999).

[9] *See, e.g.*, CX 122 at SP 23 00295 (6/5/97 Schering projections regarding impact of generic K-Dur 20).

[10] *See, e.g.*, CX 149 (4/97 Upsher-Smith document projecting substantial downturn in K-Dur 20 sales as a result of Upsher's generic K-Dur 20 entry).

- Upsher-Smith asked for compensation in exchange for agreeing to stay off the market.[11]

- Schering concluded that compensating Upsher-Smith for staying off the market was "a prerequisite to any deal."[12]

- [redacted].[13]

- [redacted].[14]

- Schering saw a problem with a naked payment and [redacted].[15]

- The $60 million in non-contingent cash payments was "totally out of whack" and far greater than any non-contingent cash license fee that Schering had ever paid, even for products whose projected sales far exceeded the estimates for Niacor-SR. Tr. 7:1329-30 (Levy).[16]

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[11] CX 1529 (Troup IH at 111-12).

[12] CX 338 at SP 12 00270 (1997 memorandum to Schering's Board of Directors).

[13] CX 338; CX 283 at SP 018780 [in camera] [redacted].

[14] *See* Tr. 4:663 (Bresnahan) (present value of Schering's June 1997 promise to pay $60 million over two years was $54.5 million).

[15] CX 338 at SP 00268 (Schering representatives had advised Upsher-Smith that an arrangement to replace Upsher-Smith's loss of anticipated income from generic entry would have to "stand on its own merit, independent of the settlement"); CX 283 at SP 018780 [in camera] [redacted].

[16] *See also* Tr. 7:1336 (Levy) ("$60 million was so grossly excessive that I would not think it could reasonably have been for Niacor-SR"; 7:1395-96 (Levy) ("$60 million payment is. . . much larger than any payment Schering-Plough ever made"); 7:1513-14; 7:1522-23 (Levy) [in camera].

- Schering's due-diligence process that led to this unusual non-contingent payment was extraordinarily superficial, particularly given Schering's normal practices. Tr. 7:1307 (Levy); 7:1492-1527 [in camera].

- The parties' post-agreement behavior is inconsistent with any suggestion that Schering was serious about developing Niacor-SR. From the outset, Schering devoted few resources to the project and had very little communication with Upsher-Smith. Tr. 7:1307; 1379-1394; 1396 (Levy).

This case does not challenge the licenses themselves, notwithstanding repeated claims by Upsher-Smith and Schering that we have asserted and must prove that their license agreement was a "sham."[17] And our case does not require that we establish the "quantitative value" of the Niacor-SR license and other licenses Upsher-Smith conveyed to Schering, as Upsher-Smith claims.[18] We do not contend that the Upsher-Smith products that were licensed had no value. Indeed, Dr. Levy testified that the terms of the license agreements are unremarkable in all respects save one: the huge, non-contingent payment. Tr. 7:1136-37 (Levy). We merely contend that the licenses do not explain the $60 million in non-contingent payments to Upsher-

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[17] *See, e.g.*, Tr. 1:84-85, 100 (opening statement of Mr. Curran); Tr. 1:58 (opening statement of Mr. Nields); Respondent Schering-Plough's Pretrial Brief (January 15, 2002) at 20, 23.

[18] Although Upsher-Smith suggests that Professor Bresnahan's analytical framework requires proof of a quantitative valuation of the licenses, that is plainly not the case. Dr. Bresnahan concluded that the $60 million was not for Niacor-SR, based on Dr. Levy's analysis and other evidence. In deciding whether there was a payment of net consideration in this case, he determined that the relevant questions are: (1) whether Schering would have paid Upsher-Smith $60 million in non-contingent payments if it were not also getting Upsher-Smith's agreement to the 2001 entry date; and (2) whether Upsher-Smith could have received an unconditional payment of that magnitude absent the settlement. Tr. 6:1231-32. The non-contingent nature of the large, up-front cash payments from Schering was an important consideration that led him to conclude that these payments were not for Niacor-SR and thus that "net value" was paid to Upsher-Smith, notwithstanding the "present value" of Schering's sales projections, Tr. 5:1012-1014.

Smith. The case-in-chief evidence amply supports that conclusion, and our anticipated rebuttal case will further confirm it.

Having made a prima facie showing of a payment for an agreement to stay off the market for several years – conduct that obviously is likely to have anticompetitive effects – the burden now shifts to the respondents to come forward with a plausible procompetitive justification.[19] Respondents will fail to meet that burden. Their principle defense – that the $60 million payment to Upsher-Smith was for the Niacor-SR license – is not a justification for the payment not to compete, but a claim that there was no such payment. Any argument that such a payment promotes competition will merely be post-hoc rationalization.

In its motion, Upsher-Smith complains that we have not proven that the agreement had a net anticompetitive effect, after weighing the asserted procompetitive effects of the agreement against its anticompetitive effects. But analysis of net competitive effects is not part of the prima facie case. How could it be? Assessment of net competitive effect (if even necessary) can, by definition, occur only after any procompetitive justifications proffered by respondents have been assessed.[20]

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[19] *See, e.g., California Dental Ass'n v. FTC*, 526 U.S. 756 (1999); *See generally* XI Herbert Hovenkamp, Antitrust Law ¶ 1914 (2000) (discussing burden and elements of proof in horizontal restraints cases) and VII Phillip E. Areeda, VII Antitrust Law ¶ 1511 (1986) (discussing collapsing reasonableness-per se distinctions).

[20] Upsher further claims that we failed to establish a prima facie case because we did not prove that (1) Upsher's 180-day exclusivity period kept other firms off the market, or was intended to do so, or (2) the ban on Upsher-Smith marketing any other sustained release microencapsulated potassium chloride tablet unreasonably restraints competition. Even if they were true, these claims would be without merit because the complaint does not plead either matter as an independent violation.

II. Direct Evidence Establishes Schering's Monopoly Power in the Market for K-Dur 20

Upsher-Smith's lengthy discussion of market definition and monopoly power in its Motion to Dismiss is premised on the erroneous assumption that the only way to prove monopoly power is by defining a relevant market, calculating market shares, and then drawing an inference of monopoly power (or its absence) from those market shares.[21] Although this approach is a respected and frequently used method of proving market power in antitrust cases, it is used when direct evidence of such power or proof of anticompetitive effects is not available. In this case, however, there is abundant record evidence here that directly proves that Schering had monopoly power in the market for K-Dur 20 at the time it entered into its agreement with Upsher-Smith in 1997. Consequently, the market definition exercise Upsher-Smith insists upon is unnecessary as a matter of law.[22] But even if it were necessary to define a relevant market as Upsher-Smith

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[21] For the purpose of this response to Upsher-Smith's Motion to Dismiss, we adopt the convention, frequently employed by economists, of using the terms monopoly power and market power interchangeably. *See generally* Dennis W. Carlton and Jeffrey M. Perloff, *Modern Industrial Organization*, (3rd ed. 1999) at 92, ("[t]he terms *monopoly power* and *market power* typically are used interchangeably to mean the ability to profitably set price above competitive levels ([i.e.,] marginal cost)") (emphasis in original). We note, however, that as a matter of law, market power is considered less substantial than monopoly power, thus requiring a lower threshold of proof, and that the antitrust violations alleged in the complaint in this case paralleling Sherman Act § 1 theories require only proof of market power or likely competitive effects, not monopoly power. *See generally* 3A Phillip Areeda and Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶ 801 at 300 (rev. ed. 1996) (monopoly power is conventionally understood to mean "substantial" market power).

[22] The consequence of using the market definition methodology to infer monopoly power in a market where a monopolist already exercises its power typically is to erroneously conclude that the relevant market is much larger than it actually is (because substitution is mistakenly taken for competition), and it is likely to lead to the erroneous conclusion that a monopolist is not a monopolist. *Cf.* Dennis W. Carlton and Jeffrey M. Perloff, *Modern Industrial Organization*, (3rd ed. 1999) at 614 (discussing the cellophane fallacy and the difficulties that may arise in

(continued...)

contends, K-Dur 20 and its generic equivalents is a relevant market within which to analyze the effects of the challenged agreement.

A. Courts Use Direct Evidence to Assess Monopoly Power

Monopoly power, according to the Supreme Court, "is the power to control prices or to exclude competition."[23] This power can be established in a number of ways.

> One type of proof is direct evidence of the injurious exercise of market power. If the plaintiff puts forth evidence of restricted output and supracompetitive prices, that is direct proof of injury to competition which a competitor with market power may inflict, and thus of the actual exercise of market power. The more common type of proof is circumstantial evidence pertaining to the structure of the market. To demonstrate market power circumstantially, a plaintiff must: (1) define the relevant market, (2) show that the defendant owns a dominant share of that market, and (3) show that there are significant barriers to entry and show that existing competitors lack the capacity to increase their output in the short run.[24]

As the Seventh Circuit Court of Appeals has elaborated: "Market share is just a way of estimating market power, which is the ultimate consideration. When there are better ways to estimate market power, the court should use them."[25] This echoes the Supreme Court's teaching

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[22] (...continued)
defining markets).

[23] *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956) (footnote omitted).

[24] *Rebel Oil Co, Inc. v. Atlantic Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995) (citations omitted). *See also Flegel v. Christian Hosp.*, 4 F.3d 682, 688 (8th Cir. 1993) ("Since the purpose of the inquiries into market definition and market power is to determine whether the arrangement has the potential for genuine adverse effects on competition, 'proof of actual detrimental effects, such as a reduction of output," can obviate the need for an inquiry into market power, which is but a 'surrogate for detrimental effects.'" (quoting *Indiana Fed'n*, 476 U.S. at 461, 106 S.Ct. 2009).

[25] *Ball Memorial Hospital, Inc. v. Mutual Hospital Insurance, Inc.*, 784 F.2d 1325, 1336 (7th Cir. 1986)(Easterbrook, J.), *reh'g en banc denied*, 788 F.2d 1223 (7th Cir.1986) (citation (continued...)

in *FTC v. Indiana Fed'n of Dentists*, where the Court wrote: "[s]ince the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, proof of actual detrimental effects . . . can obviate the need for an inquiry into market power, which is but a surrogate for detrimental effects."[26]

In this case there is better (direct) evidence of Schering's substantial market power than the circumstantial evidence Upsher-Smith would have this Court rely upon. The direct evidence of anticompetitive effects in this case, which clearly demonstrates Schering's monopoly power in the market for K-Dur 20 at the time it entered into its agreement with Upsher-Smith, obviates any need to engage in the market definition exercise Upsher-Smith advocates.

B. There is Ample Direct Evidence of Schering's Monopoly Power and the Anticompetitive Effects of the Agreement with Upsher-Smith

That Schering enjoyed monopoly power in the market for K-Dur 20 at the time it entered into its agreement with Upsher-Smith is established by: (a) forecasts by Schering, Upsher-Smith, and AHP concerning the significant impact generic K-Dur 20's entry would have on the sales and the average price of K-Dur 20 and its generics; and (b) the insubstantial competitive effects that other potassium supplements had on K-Dur 20's sales or pricing prior to generic entry. Moreover, this conclusion is consistent with abundant economic literature on pharmaceutical competition, and it is supported by the market effect that generic K-Dur 20's entry actually had. Taken together this evidence establishes that Schering enjoyed significant market power in the

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[25] (...continued)
omitted).

[26] 476 U.S. 447, 460-61 (1986) (citation and internal quotation marks omitted).

market for K-Dur 20 at that time of its agreement with Upsher-Smith, and that Upsher-Smith's agreement with Schering had significant potential for harming competition and consumers at the time it was entered in 1997.

1. The Forecasts by Schering, Upsher-Smith, and AHP

Under competitive conditions, a profit-maximizing firm sells its product at a price that is equal to its marginal cost of production.[27] In contrast, a firm with market power is able to price above marginal cost, and one with monopoly power may be able to price substantially above marginal cost. "Pricing above marginal cost" is simply an economic formulation of the Supreme Court's definition of monopoly power set out in *du Pont*: "the power to control prices."[28]

The many market forecasts prepared independently by Schering, Upsher-Smith, and ESI Lederle before the settlements at issue in this case make remarkably similar projections about the significant impact that generic K-Dur entry's would have on branded K-Dur's sales, and on the market price of K-Dur 20 and its generics. They show unequivocally that prior to generic entry Schering was able to make all of its sales of K-Dur 20 at prices well above marginal cost. Consequently, these projections directly demonstrate Schering's substantial "power to control prices" of K-Dur 20, prior to generic competition.

- The projections – whether prepared by Schering, Upsher-Smith, or ESI Lederle – show that generic K-Dur 20 was expected to be priced 50% below branded K-Dur 20, and yet

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[27] IIA Phillip E. Areeda, Herbert Hovenkamp, and John L. Solow, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* (2nd ed.2002) ¶ 503 at 91 (marginal cost reflects the cost that results from producing an additional unit of output).

[28] *See In re Brand Name Prescription Drugs Antitrust Litigation*, 1999 U.S. App. LEXIS 15621 (7th Cir. 1999) at *2 (Posner, J.) (defining market power as "the power to charge a price above cost (including in 'cost' a profit equal to the cost of equity capital) without losing so much business so fast to competitors that the price is unsustainable").

the generics would still be sold at a profit. *See, e.g.*, CX 150 (Notes of Denise Dolan, Upsher-Smith's Marketing Manager for Klor Con M20, July 1997, estimating "that our [average selling price] would be 50% less than K-Dur 20"); CX 169 at AHP 13 00168-84 (ESI's "K-Dur Analysis," Sep. 3, 1997) which shows that ESI "too thought that there would be substantial impact from generic entry."[29] Tr. 3:461 (Bresnahan).

- Other Schering marketing documents show that Schering even planned to offer its own generic K-Dur, through its Warrick subsidiary, at a [redacted] branded K-Dur's price. *See, e.g.*, CX 133 at SP 25 00004 [in camera] [redacted].[30]

- The projections also consistently show that generic K-Dur 20 is expected to take from [redacted] branded K-Dur's sales within months of entry. *See, e.g.*, CX 133 at SP 00004 [in camera] [redacted] half [redacted]; *see also* CX 18 at SP 23 00044 (Schering "1997 K-Dur Marketing Plan," Sep. 10, 1996, prepared by Schering's Marketing Manager for K-Dur, Christopher Di Lascia, stating that: "Although generic entry is not likely until 1998 the impact of a generic 20 mEq product would be significant, especially for sales subject to mandatary generic substitution laws, Medicaid, and managed care.").

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

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[29] We have refrained from citing specific data from this document because it currently is subject to *in camera* treatment.

[30] One may ask, why would a branded drug company also launch a generic of its own product? This is done because when generic competition is imminent, this practice can increase the branded firm's profits by allowing it to charge a high price to buyers who value the product the most (those customers who insist on staying with the brand and are willing to pay the higher price for it), while still making profits from sales of the lower-priced generic to the majority of buyers who are no longer willing to pay the full, branded price. In economic terms, this practice is known as "price discrimination;" which may be defined as "selling the identical product to different customers at different prices even though the manufacturer's cost of selling them is the same." *See In re Brand Name Prescription Drugs Antitrust Litigation*, 1999 U.S. App. LEXIS 15621 (7th Cir. 1999) at *2 (Posner, J.). As Judge Posner observed in *In re Brand Name Prescription Drugs*, "[p]rice discrimination implies market power." *Id.*

This evidence establishes conclusively that Schering had the power to control the price of K-Dur 20 at the time it entered into its agreement with Upsher-Smith in 1997, and that Upsher-Smith knew this.

2. The Insubstantial Effects that Other Potassium Supplements Had on K-Dur 20's Sales or Pricing

We readily acknowledge (as did Professor Bresnahan) that prior to generic K-Dur 20's entry, there were many other potassium chloride products offered for sale in the United States, including generic 8 and 10 mEq products. As the Commission made clear in *Coca-Cola Bottling Company of the Southwest*, the relevant inquiry is not whether "certain [products] 'competed' against each in a broad sense" but instead whether such "products were sufficiently substitutable that they could constrain" each other's pricing.[31] Here, there is abundant direct, record evidence – evidence Upsher-Smith has largely chosen to ignore in its motion – demonstrating that branded K-Dur 20 "commanded a substantial price premium over – over the then existing generics." Tr. 3:475 (Bresnahan).[32] Indeed, we cannot say it any better than Schering's Andrea J. Pickett, the product manager for K-Dur 20, did in 1995, when she wrote: "K-DUR is priced 40-50% higher than a comparable generic dose. However, K-DUR's growth has not been significantly impacted by the prevalence of generics in the Therapeutic Class . . . ."[33] Moreover, despite K-Dur 20's

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[31] *In the Matter of Coca-Cola Bottling Company of the Southwest*, 118 F.T.C. 452, 542 (1994) (admonishing the ALJ for his "narrow focus on certain selected pieces of evidence" and reversing the initial decision).

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

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

price being as much as 30% above generic K-Dur 8 and 10, K-Dur 20's unit sales were growing "substantially faster than other potassium chloride products even though you have to pay more to get one K-Dur 20 than you need to pay to get two of the 10 milliequivalents." Tr. 3:476 (Bresnahan).[34]

The testimony by Upsher-Smith executives and the contemporaneous business documents of Schering offer two reasons why K-Dur 20's sales were growing prior to generic entry, despite the fact that it was priced significantly higher than products Upsher-Smith argues in its motion are comparable. First, K-Dur's 20 mEq formulation offers convenience to the patient and patient compliance to the physician.

- Denise Dolan, Upsher-Smith's marketing manager for Klor Con M20, testified: "my educated assumption was that the market was trending towards the 20 mEq because of ease of dosing and patient compliance."[35]

- Similarly, Phillip Dristas, Upsher-Smith's marketing executive, testified: "the 20 mEq has such a large dollar volume and really is such a convenient product for patients . . . ." Also "if you can swallow it whole rather than taking two tablets, you could take one and some people are absolutely willing to pay more for that convenience."[36]

- In the "1998 K-Dur Marketing Plan," prepared by Schering's marketing manager for K-Dur, Christopher Di Lascia, wrote: "K-DUR 20 remains the only once daily, 20 mEq potassium replacement tablet on the market. These features, combined with the versatility in dosing from K-DUR 20's microencapsulation technology have helped our sales and marketing team keep K-DUR 20 without peer in the potassium market."[37]

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[34] *See, e.g.*, CX 18 at SP 23 00040 ("K-DUR sales continue to increase, up 20% from the previous year").

[35] CX 1493 at 30 (Dolan dep.).

[36] CX 1496 at 40 (Dristas dep.).

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

- Then again in the "1999 K-Dur 20 mEq Marketing Plan," also prepared by Schering's marketing manager for K-Dur, Christopher Di Lascia, writes: "**K-DUR 20 mEq – there is no substitute** – consistent replacement and ensured patient safety since K-DUR 20 mEq cannot be substituted with a variety of generics" (emphasis in original); and also: "**K-DUR 20 mEq is the only once-a-day 20 mEq potassium replacement available in a single tablet** – physicians can be assured that patients will not be taking subtherapeutic doses, i.e., through 'self-prescribing' 10 mEq."[38]

Second, pharmacies cannot automatically substitute other dosage forms of potassium chloride for K-Dur 20. As Professor Bresnahan explained, this imposes what economists call a "switching cost" on those who seek to use a non-bioequivalent generic or other potassium chloride product in lieu of K-Dur 20. Tr. 3:490-91 (Bresnahan).

- In its "Klor-Con M20" Plan, Denise Dolan, Upsher-Smith's marketing manager for Klor Con M20, wrote: "Klor-Con M20 Tablets are potassium chloride extended-release tablets that are therapeutically and fully substitutable for K-Dur 20. Klor-Con M20 is positioned to be the first quality, low cost alternative to K-Dur 20 representing a better value to the pharmacist."[39]

- Similarly, in the "1997 K-Dur Marketing Plan," Schering's marketing manager for K-Dur, Christopher Di Lascia, wrote: "Although generic entry is not likely until 1998 the impact of a generic 20 mEq product would be significant, especially for sales subject to mandatary generic substitution laws, Medicaid, and managed care."[40]

3. The Economic Literature on Pharmaceutical Industry Competition

As complaint counsel's economic expert, Professor Bresnahan, testified, the economic literature provides additional support for the proposition that the sales of generic drugs come almost entirely at the expense of their branded counterparts, while having little if any impact on

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[38] CX 22 at SP 23 00080 ("1999 K-Dur 20 mEq Marketing Plan," Sep. 28, 1998).

[39] CX 364 at USL 12832 ("Klor-Con M20 Plan," July 1997).

[40] CX 18 at SP 23 00044 ("1997 K-Dur Marketing Plan," Sep. 10, 1996).

the sales or price of other branded products.[41] *See generally* Tr. 3:495 (Bresnahan). The empirical research demonstrates that when a generic drug enters the market it is priced well below its branded counterpart, with the first generic entrant coming in at a price, on average, 25% lower than the brand's price.[42] For each generic entrant thereafter, generic prices continue to fall between 5% and 7%.[43] These same studies have documented the rapid erosion of a branded drug's sales once a generic version is introduced. For example, a Congressional Budget Office study using a sample of drugs that first faced generic competition between 1991 and 1993 shows that within a year of entry the generic drugs captured roughly 44% of the prescriptions dispensed by pharmacies for the respective drug.[44] Similarly, another study using a sample of drugs whose patents expired between 1989 and 1992 found that generics, on average, took 50%

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[41] *See, e.g.*, Henry Grabowski and John Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act," J. L. & Econ. (Oct. 1992); Richard G. Frank and David S. Salkever, "Generic Entry and the Pricing of Pharmaceuticals," J. Econ. & Mgmt. Strategy (Spring 1997); Richard Caves, M. Whinston, and M. Hurwitz, "Patent Expiration, Entry and Competition in the U.S. Pharmaceutical Industry," Brookings Papers on Economic Activity: Microeconomics, 1991; Office of Technology Assessment, "Pharmaceutical R&D: Costs, Risks, and Rewards," U.S. GPO, 1993; Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Market," Washington, D.C. 1998; Roy Levy, "The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change," Federal Trade Commission, Bureau of Economics Staff Report, 1999.

[42] Office of Technology Assessment, "Pharmaceutical R&D: Costs, Risks, and Rewards," U.S. GPO, 1993.

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

[44] Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Market," Washington, D.C. 1998.

of the share of prescriptions sold within one year of entry.[45]

The implication of this empirical research in terms of assessing the anticompetitive effects from delaying generic entry is that when generic products are able to enter the market, a substantial segment of consumers avail themselves of the lower-priced generic products, thereby realizing significant cost-savings of 25% or more relative to the pre-entry period.

4. The Evidence That Lower-Priced Generic K-Dur 20 Has Taken Substantial Sales from K-Dur 20

Sales data from the first four months since generic K-Dur 20's entry show that "there was a very substantial switch from K-Dur 20, the branded product, to generics." Tr. 3:472 (Bresnahan). By November 2001, a mere three months after Upsher-Smith finally entered the market, there were "more prescriptions dispensed for the generics than for the brands." Tr. 3:473 (Bresnahan). This evidence shows that "what had been projected came true," and it "shows the monopoly power" Schering enjoyed prior to generic entry. Tr. 3: 470, 473.

Why do sales of a generic drug come almost entirely at the expense of its branded counterpart, while having little if any impact on the sales or price of other branded products? The simple answer is: state generic drug substitution laws. Most states have laws that allow pharmacists to automatically substitute a generic drug for its branded equivalent, and some states even require it.[46] The only exception in these laws occurs when a physician writes "Dispense as

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[45] Henry Grabowski and John Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act," J. L. and Econ. (October 1992).

[46] *Compare* Mich. Stat. Ann. § 333.17755(1) (West, WESTLAW through 2001 P.A. 2001, No. 114 of the 2001 Regular Sess.) ("[T]he pharmacist may . . . dispense a lower cost but not higher cost generically equivalent drug"), *with*, Conn. Gen. Stat. Ann. § 17b-274 (West, WESTLAW through Jan. 1, 2001) ("A pharmacist shall dispense a generically equivalent drug (continued...)

Written," or "DAW," on the prescription.[47] Many health plans and payers, in turn, encourage or insist on the use of generic drugs rather than their branded equivalent wherever possible, creating an immediate market for the generic equivalents of branded products.[48] Because of these laws, generics compete on price alone, and branded drugs effectively become commoditized overnight.

At the same time, no states allow for the substitution by pharmacies between branded drugs and their generics with other branded drugs and their generic equivalents, even where the drugs contain precisely the same active pharmaceutical ingredient in the exact same dosage strength.

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[46] (...continued)
product for any drug listed in accordance with the Code of Federal Regulations Title 42 Part 447.332 for a drug prescribed for a Medicaid, state-administered general assistance, or ConnPACE recipient").

[47] *See, e.g.*, Mich. Stat. Ann. § 333.17755(3) (West, WESTLAW through 2000 Regular Sess.) ("The pharmacist shall not dispense a generically equivalent drug product under subsection (1) if . . . [t]he prescriber . . . writes . . . 'dispense as written' or 'd.a.w.' on the prescription.").

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

C. K-Dur 20 and Its Generic Equivalents is a Relevant Market Within Which to Analyze the Effects of the Challenged Agreement

Prior to generic K-Dur's entry, there is little doubt that Schering's K-Dur 20 "competed" to some extent with other pharmaceutical products, in the sense that there were numerous therapeutic agents that could be used to treat potassium deficiency ("hypokalemia"). A properly defined relevant antitrust product market, however, as a matter of law, need not include all functionally interchangeable products, as Upsher-Smith suggests in its motion. Rather, as the Supreme Court has made clear, the functional interchangeability between products provides only "the outer boundaries of a product market."[49] When products, like pharmaceuticals, can be used for the same purpose but differ in terms of price, quality, consumer preferences, or other significant attributes, the products are considered to be differentiated. And, although differentiated products "compete" along some dimensions, as the Third Circuit Court of Appeals recognized in *Smith-Kline Corp. v. Ely Lilly & Co.*, a case involving the pharmaceutical industry, a relevant antitrust market should include only those products that "have the ability actual or potential to take significant amounts of business away from each other."[50] As set forth in detail

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

[50] *SmithKline Corp. v. Ely Lilly & Co.*, 575 F.2d 1056, 1063 (3d Cir. 1978). *See also FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1077 (D.D.C. 1997) ("[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"). Similarly, the Commission and the courts have routinely found that a demonstrated ability to charge significantly different prices for functionally interchangeable products is sufficient to prove that the products are in separate antitrust markets. *See, e.g., In the Matter of Coca-Cola Bottling Company 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); *In the Matter of the Olin Corp.*, 113 F.T.C. 400, 604 (1990) (excluding liquid pool sanitizers from a dry pool sanitizer market); *SmithKline Corp.*, 575 F.2d at 1065 (excluding non-cephalosporin antibiotics as well as other anti-infective (continued...)

above, only generic K-Dur 20 had the potential to take significant amounts of business away from Schering's K-Dur 20. No other potassium chloride product could do what Upsher-Smith's generic version of K-Dur 20 did.

D. Conclusion: The Illegal Agreement Defines the Market

The relevant market in which to analyze the competitive effects of Schering's agreement with Upsher-Smith is the sale of K-Dur 20 and its generic equivalents in the United States. This is based primarily on direct evidence in the record that sales of generic K-Dur 20 come almost entirely at the expense of Schering's K-Dur 20, while having little if any impact on the sales or price of other potassium chloride products. While we recognize that this market excludes other potassium chloride supplements that have the same active pharmaceutical ingredient as K-Dur 20, this market accurately reflects the unique competitive dynamic that typically exists between a branded drug and its generic counterpart.[51] Indeed, it is precisely this unique competition – the

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[50] (...continued)
drugs from a cephalosporin antibiotic market); *Staples*, 970 F. Supp. at 1078 (defining office superstores as a relevant product market and excluding wholesale clubs, discount retailers, and office supply stores); *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).

[51] Although Upsher-Smith's counsel appears to be in denial, Schering's counsel, Mr. Nields, readily acknowledges the unique nature of competition between a branded drug and its generic equivalent, as revealed by the following sequence of questions Mr. Nields asked during his cross-examination of Professor Bresnahan:

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

(continued...)

fact that generic entry commoditizes its branded equivalent literally overnight – that explains why Schering was willing to pay Upsher-Smith millions of dollars to delay generic entry.

Upsher-Smith, however, insists the only relevant market is one consisting of all potassium chloride supplements and that K-Dur 20's share of that market is too small to infer monopoly power.[52] To accept Upsher-Smith's definition of the relevant market, however, one would have to conclude that the entry of generic K-Dur 20 makes little difference to competition and to consumers. Indeed, to accept Upsher-Smith's definition of the relevant market one would have to conclude that Schering was acting irrationally when it spent millions of dollars to bring its patent lawsuit against Upsher-Smith, and that Upsher-Smith was acting irrationally when it made its investment to enter the market for K–Dur 20, including the costs of defending against Schering's patent lawsuit.

Record evidence belies Upsher-Smith's contentions. There is no doubt that patients who take generic K-Dur 20, and those who pay the bills for prescription drugs, realized significant

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[51] (...continued)

Q: Yes, I should have asked the question that way.
A: Yes.
. . .
Q: And isn't it true that the generic virtually always, if not always, underprices the brand name?
A: That's true too.
. . .
Q: And they always take sales away form the brand name, correct?
A: Yes.
Q: And indeed, by law they would almost have to.
A: I think that's right.

See Tr. 6:1176-80 (Bresnahan).

[52] *See, e.g.,* Motion to Dismiss at 18-23.

economic benefits when generic K-Dur 20 became available. There is no doubt that Upsher-Smith and Schering were aware this would be the case when they entered their illegal agreement. And there is no doubt that by delaying the entry of generic K-Dur 20 under the terms of the agreement, Schering and Upsher-Smith harmed competition and consumers.

III. Upsher-Smith Misstates the Intent Elements in this Case

Despite the broad array of evidence introduced during our case-in-chief, Upsher-Smith seeks to dismiss the complaint, arguing that complaint counsel failed to prove anticompetitive intent. (Motion at 26-27, 40-43). This argument is based on a misstatement of the applicable legal elements of the charged antitrust violations. Intent is not an element of an unlawful horizontal restraint claim, and Upsher-Smith's use of a criminal intent standard for the civil conspiracy to monopolize charge is just wrong.

A. No Proof of Anticompetitive Intent is Needed to Find that Schering's Payment to Upsher-Smith Not to Compete Unreasonably Restrains Competition

Upsher-Smith's suggestion that proof of anticompetitive intent is necessary to find a horizontal restraint unlawful under the rule of reason (Motion at 28) is incorrect for two reasons. First, Upsher-Smith's position conflicts with black letter Supreme Court law. As the Court noted in *United States v. United States Gypsum Co.*, 438 U.S. 422, 466 n. 22 (1978), in a civil antitrust action no anticompetitive intent need be proved – proof of an anticompetitive effect is sufficient. Intent evidence may be helpful to aid in the analysis of competitive effects,[53] but it is not an

[53] *Chicago Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918) (antitrust decision makers consider the purpose of a restraint "not because a good intention will save an otherwise objectionable restraint, or the reverse, but because knowledge of intent may help the court to interpret facts and to predict consequences").

essential element of proof. Second, even the case Upsher-Smith relies on to support its position, *California Dental Association v. FTC*, 224 F.3d 942, 947 (9th Cir. 2000), makes it clear that proof of anticompetitive intent is not required. In fact, just after the portion cited by Upsher-Smith, that court went on to find that, where the intent evidence is inconclusive, intent is "superfluous and "drops out" of the rule of reason inquiry.[54] Thus, the court concluded, "the case hinges on the actual economic consequences of the CDA's restrictions." 222 F.3d at 949.

B. Upsher-Smith Improperly Urges a Criminal Intent Standard For The Civil Conspiracy to Monopolize Claim

Upsher-Smith's assertion that specific intent in the civil conspiracy charge can be shown only with evidence that Upsher-Smith "consciously desired" that Schering maintain its monopoly grossly misstates the applicable standard. "[C]enturies of Anglo-American legal tradition" distinguish between the lesser showing of intent required to establish civil liability and that needed to prove criminal liability.[55] Yet, Upsher-Smith plucks its standard of intent from a criminal case arising outside the antitrust field.[56]

Even in the antitrust case cited by Upsher-Smith, *United States v. United States Gypsum*, the Supreme Court considered and then explicitly rejected the "consciously desired" intent formulation put forth by Upsher-Smith, even in the context of a criminal charge. The Court

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[54] *Id.* at 949 *citing* VII Phillip Areeda, Antitrust Law ¶ 1506.

[55] *United States v. Nippon Paper Indus. Co.*, 109 F.3d 1, 6 (1st Cir. 1997) (explaining that "criminal liability ordinarily should be premised on malevolent intent, whereas civil liability, to which less stigma and milder consequences commonly attach, often requires a lesser showing of intent") (internal citations omitted).

[56] *See* Motion to Dismiss at 40 (quoting *United States v. Gracidas-Ulibarry*, 231 F.3d 1188 (9th Cir. 2000) (attempted illegal reentry into the United States punishable by fine and imprisonment for up to two years).

found that "proof that the defendant's conduct was undertaken with knowledge of its probable consequences" was sufficient to satisfy the government's burden.[57]

In this civil case, no proof of criminal intent is needed. It is not necessary, as Upsher-Smith contends, to show that Upsher-Smith engaged in "secretive" or "furtive conduct." Nor is it required to show that Upsher-Smith's employees knew that its conduct would violate the antitrust laws. Instead, Upsher-Smith's specific intent may be established with evidence that Upsher-Smith would benefit from Schering's maintained monopoly and that Upsher-Smith "knew or should have known" that the challenged conduct would maintain that monopoly.[58] This intent may be shown either by direct evidence of Upsher-Smith's state of mind, or by inference from its conduct.

The record evidence easily establishes that Upsher-Smith knew that the agreement would maintain Schering's monopoly:

- Because the profits to the monopolist – Schering – exceed the potential economic gains to the generic entrant – Upsher – both parties stood to benefit from extending Schering's monopoly. This economic reality created a powerful incentive for Schering to pay Upsher-Smith a share of the monopoly profits to delay competitive entry. Tr. 3:424-28 (Bresnahan).

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[57] 438 U.S. 422, 444 and n. 21 (1978).

[58] *Futurevision Cable Sys's of Wiggins, Inc. v. Multivision Cable TV Corp.*, 789 F. Supp. 760, 778 (S.D. Miss.), *aff'd*, 986 F.2d 1418 (5th Cir. 1993); *see also Instructional Sys's Dev't Corp. v. Aetna Casualty and Surety Co.*, 817 F.2d 639, 647 (10th Cir. 1987) (a co-conspirator's intent can be inferred if it knew or should have known of monopolistic desires); *Syufy Enters. v. American Multicinema, Inc.*, 793 F.2d 990, 1001 (9th Cir.), *cert. denied*, 479 U.S. 1031 (1987) (specific intent can be found if co-conspirator had at least some awareness that the underlying conduct was anticompetitive or monopolistic"); *Aspen Title & Escrow, Inc. v. Jeld-Wen, Inc.*, 677 F. Supp. 1477, 1489 (D. Orc. 1987))

- Upsher-Smith knew of the dramatic impact its entry would have on Schering's profits.[59]
- Upsher-Smith asked for compensation in exchange for agreeing to stay off the market.[60]
- Upsher-Smith sought a "payment that was a percentage" of Schering's expected lost profits of K-Dur 20 in the event of generic entry – i.e., a share of Schering's monopoly rents.[61]

IV. No Proof of "What Would Have Happened" is Needed to Show that Schering's Payment to Upsher-Smith Unreasonably Restrains Competition

Upsher-Smith appears to argue that even if the $60 million payment was to secure the September 2001 entry date, the agreement still cannot be found anticompetitive unless we prove when Upsher-Smith would have entered absent the challenged conduct.[62] This argument is unavailing. Having proved that the payment was for the entry date, the inescapable conclusion is that the agreement is anticompetitive – that is, it will "always or almost always tend to restrict competition" by resulting in delayed entry.[63] Because of the inherent anticompetitive nature of these types of agreements, courts have had no trouble finding them to be horizontal agreements

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[59] *See, e.g.*, CX 149 (4/97 Upsher-Smith document projecting substantial downturn in K-Dur 20 sales as a result of Upsher's generic K-Dur 20 entry).

[60] CX 1529 (Troup IH, at 111-12).

[61] CX 1494 (Driscoll IH, at 65-67); *see also* CX 1510 (Kapur IH, at 47-49); CX 1508 (Hoffman IH, at 36).

[62] Upsher's complaint that there is no direct evidence that Schering would have agreed to an earlier entry date is also improper because, as we have pointed out elsewhere (*See* Complaint Counsel's Motions and Memorandum in Support of Motion to Preclude Certain Testimony of Respondents' Lawyer Witnesses (Feb. 5, 2002)), the parties' privilege claims have made it impossible for us to inquire into what alternatives to the settlement were considered. Respondents, thus, are precluded from relying on the absence of evidence on this point to support an inference that no other settlement was possible.

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

not to compete, and *per se* illegal.[64] Uncertainty about when Upsher-Smith would have entered absent the settlement does not undermine the anticompetitive nature of conduct that, at the time it was entered into, was likely to delay generic entry.[65] To reach any other conclusion would be to ignore basic economics and common sense. Why would Schering pay Upsher-Smith $60 million for an entry date if that entry date was, in fact, earlier than the entry date that would have occurred in the absence of any payment? It is for this reason that other courts have found that a payment from a brand manufacturer to an allegedly infringing would-be generic entrant logically indicates that the payment is for delayed generic competition.[66]

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[64] *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); *In re Terazosin Hydrochloride Antitrust Litigation*, 164 F.Supp.2d 1340, 1349 (S.D. Fla. 2000), *appeal pending*.

[65] *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001) (per curiam) (Section 2 prohibits monopolist's exclusionary conduct directed toward nascent competitive technologies, even in the absence of proof that those technologies would have developed into viable substitutes) ; *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 256 F.3d 799 (D.C. Cir. 2001) (exclusionary conduct directed toward potential generic entrant stated a cause of action under the antitrust laws, even though the entrant did not yet have FDA approval for its product); *Microbix Biosystems, Inc. v. BioWhittaker, Inc.*, 172 F. Supp. 2d 680 (D. Md. Mar. 28, 2000), *aff'd on other grounds*, No. 00-2262, 2001 WL 603416 (4th Cir. Jun. 4, 2001) (exclusionary conduct could be condemned under the rule of reason, even though subsequent events made it impossible for the target of the conduct to enter the market in any event).

[66] *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 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).

V. The Conspiracy Element is Proven By The Written Agreement

Proof of a conspiracy does not, as Upsher-Smith asserts, require evidence of "furtive conduct." (Motion at 43-44). To the contrary, establishing this element of the conspiracy to monopolize claim requires nothing more than evidence of an agreement, joint venture, or other form of concerted action. As one leading antitrust treatise explains:

> The words 'combine' and 'conspire' in Section 2 of the Sherman Act are not distinguishable from the words 'combination' or 'conspiracy' used in Section 1. Each of those words connotes the existence of concerted, as opposed to individual, action.[67]

There is no dispute that Schering and Upsher-Smith entered into a written agreement.[68] No additional evidence is required to prove the conspiracy.

VI. Patent Law Does Not Permit a Patent-Holder to Pay a Potential Competitor Not to Compete

Upsher-Smith's contention that the complaint should be dismissed on the theory that Schering was merely enforcing its patent rights (Motion at 44-46) is just as wrong now as it was when Upsher-Smith made in its prior motion to dismiss back in July, 2001.[69] Patent-holders are entitled to enforce their patents, to refuse to license them to others, and to grant licenses with

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[67] 2 Julian O. Von Kalinowski, *Antitrust Laws and Trade Regulation*, §26.02[2] at 26-32 to 33 (2001); *see also* VI Phillip E. Areeda, *Antitrust Law*, §1403 at 17 ("The courts sometimes speak of 'combination,' sometimes of 'conspiracy', or sometimes simply of 'agreement.' They usually use these terms interchangeably, and the use of one term does not imply any distinction between them").

[68] CX 348.

[69] *See Order Denying Motions of Respondents Schering-Plough and Upsher-Smith to Dismiss the Complaint* (Oct. 31. 2001).

certain restrictions.[70] But these principles do not mean that a patent holder is entitled to pay a potential competitor not to compete. The Supreme Court has condemned anticompetitive agreements between parties with an unresolved patent dispute, notwithstanding the possibility that the patent holder might have been able to secure a court judgment that would have excluded all competition from the alleged infringer for the life of the patent.[71]

Upsher-Smith cites no authority that a patent holder has the right to pay a potential competitor not to enter the market. The cases that Upsher-Smith cites concern the legality of

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

> A patentee has the exclusive right to manufacture, use, and sell his invention. The heart of his legal monopoly is the right to invoke the State's power to prevent others from utilizing his discovery without his consent. The law also recognizes that he may assign to another his patent, in whole or in part, and may license others to practice his invention. But there are established limits which the patentee must not exceed in employing the leverage of his patent to control or limit the operations of the licensee.

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

limitations and conditions that a patent holder may impose in licenses it grants to others.[72] This body of case law has nothing to do with the conduct challenged in this case.

VII. This Case Is Not Moot

To justify dismissal at this point in the proceeding, without an adjudication of the legality of the challenged conduct, Upsher-Smith would have to demonstrate that this case is moot. It is plainly not enough to rest on the ground that certain aspects of the relief included in the complaint's "Notice of Contemplated Relief" can no longer be granted. (Motion at 46.) As the Supreme Court made clear in *United States v. W.T. Grant*, 345 U.S. 629 (1953), even a total abandonment of the allegedly unlawful conduct would not make the case moot:

> [V]oluntary cessation of allegedly illegal conduct does not deprive the tribunal of the power to hear and determine the case, *i.e.*, does not make the case moot. A controversy may remain to be settled in such circumstances, *e.g.*, a dispute over the legality of the challenged practices. The defendant is free to return to his old ways. This together with a public interest in having the legality of the practices settled, militates against a finding of mootness. For to say that a case has become moot means that a defendant is entitled to dismissal as a matter of right. The

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[72] For example, the Supreme Court has established a general rule that a licensor may impose conditions in the grant of a license, including conditions relating to the price at which the licensee can sell the product. On the other hand, it is clearly established that the antitrust laws apply to efforts by the patent holder to establish the prices at which purchasers of the patented products can resell the products to others. Such actions, among others, are deemed to exceed the rights granted by the patent law. *See, e.g., Ethyl Gasoline Corporation v. United States*, 309 U.S. 436, 452 (1940). Other cases cited in Upsher-Smith's motion do not involve antitrust claims at all, but rather the assertion of patent misuse claims as a defense in an action for infringement or for payment of royalties. *Dawson Chemical Co. v. Rohm and Haas Co.*, 448 U.S. 176 (1980) (patent misuse asserted as defense in a claim for contributory infringement); *Brulotte v. Thys Co.*, 379 U.S. 29 (1965) (license agreement requiring payment of royalties after expiration of the patent constitutes patent misuse, and the agreement is unenforceable with respect to post-expiration royalties).

> courts have rightly refused to grant defendants such a powerful weapon against public law enforcement.[73]

Upsher-Smith does not purport to be able to demonstrate true mootness that would warrant dismissal of the complaint without an adjudication of the legality of its conduct. It claims only that complaint counsel cannot show an order is warranted. This argument, even if it were correct, provides no basis for dismissal of the complaint at this stage of the proceeding.

Moreover, as we will discuss more fully in our post-trial brief, the evidence amply shows the "cognizable danger of recurrent violation" needed to support an order prohibiting similar agreements in the future. For example:

- The unlawful conduct was not abandoned. On the contrary, the agreement was fully carried out. While a spontaneous and voluntary abandonment of past conduct that might suggest an intent to avoid similar unlawful conduct in the future, we have no such conduct here.[74]

- There has been no change in market conditions that would suggest future violations are unlikely.[75] For example, neither Upsher-Smith nor Schering has exited the pharmaceutical business.

- Respondents have not disavowed their challenged conduct, further demonstrating that they may enter into similar agreements in the future.[76]

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[73] 345 U.S. at 632 (footnotes and citations omitted). The burden is on the defendant to demonstrate that its abandonment makes the proceeding moot. *Id.* at 633.

[74] *See. e.g., United States v. Oregon Medical Society*, 343 U.S. 326, 334 (1952) (injunction unwarranted where anticompetitive activities ceased seven years before complaint issued).

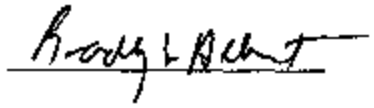
[75] *See, e.g., Borg-Warner Corp. v. FTC*, 746 F.2d 108, 110 (2d Cir. 1084) (respondent sold auto parts division, eliminating interlocking directorate); *International Harvester*, 104 F.T.C. 949, 1047-50 (1984) (change in tractor technology made recurrence of violation unlikely).

[76] *See, e.g., American Medical Ass'n v. FTC*, 638 F.2d 443, 451 (2d Cir. 1980), *aff'd by an equally divided Court*, 455 U.S. 676 (1982) (order within FTC's discretion where AMA failed (continued...)

VIII. Conclusion

For the reasons discussed above, we request that the Court deny Upsher-Smith's motion to dismiss.

Respectfully submitted,



Karen G. Bokat
Bradley S. Albert
Elizabeth Hilder
Markus H. Meier
Judith Moreland

Counsel Supporting the Complaint

Dated: March 4, 2002

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[76] (...continued)
to disavow challenged policies).

CERTIFICATE OF SERVICE

I, Andrew S. Ginsburg, hereby certify that on March 4, 2002:

I caused copies of the public version of Complaint Counsel's Opposition to Upsher-Smith's Motion to Dismiss to be served upon the following persons by hand delivery-

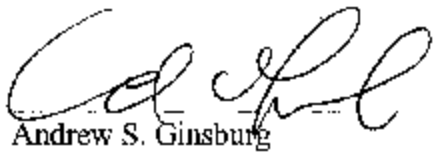
Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Laura S. Shores, Esq.
Howrey Simon Arnold & White
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2402

Christopher M. Curran, Esq.
White & Case LLP
601 13th Street, N.W.
Washington, D.C. 20005

I caused one original and one copy of the public version of Complaint Counsel's Opposition to Upsher-Smith's Motion to Dismiss to be served by hand delivery and one copy to be served by electronic mail upon the following person-

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



Andrew S. Ginsburg