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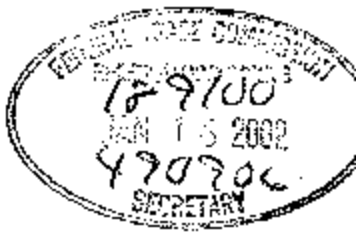
January 16, 2002



BY HAND

Donald S. Clark
Secretary
Federal Trade Commission - Office of the Secretary
6th and Pennsylvania Avenue, N.W., Rm. 172
Washington, D.C. 20580

Re: Schering-Plough Corp., Upsher-Smith Laboratories, Inc., American Home Products Corporation, Docket No. 9297

Dear Secretary Clark:

Enclosed please find the original and one copy of the public version of Upsher-Smith's Trial Brief, as well as a copy of the protective order in this matter. The confidential version of Upsher-Smith's Trial Brief was filed yesterday.

We will provide an electronic copy of the above-referenced pleading by e-mail later today.

Sincerely,

Peter J. Carney

Enclosures

cc: Laura S Shores, Esq.
Karen G. Bokat, Esq.

ORIGINAL

UNITED STATES OF AMERICA
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

UPSHER-SMITH'S TRIAL BRIEF

Through substantial investment and dogged determination, Upsher-Smith won the right to introduce generic competition to Schering's K-Dur 20 on September 1, 2001 — more than five years before the September 5, 2006 expiration of Schering's '743 patent. Contrary to the allegations of the Complaint, Upsher-Smith did not accept any money from Schering to "delay" generic competition. In fact, Upsher-Smith did everything in its power to *accelerate* generic competition as much as possible.

Upsher-Smith looks forward to the opportunity to vindicate itself at trial. In this brief, Upsher-Smith previews the facts that it will prove at trial and the legal principles that govern this proceeding.

I. AT TRIAL UPSHER-SMITH WILL ESTABLISH THAT IT ACCELERATED GENERIC COMPETITION

Consumers today are enjoying low-priced generic alternatives to Schering's K-Dur 20, even though Schering's patent covering the product does not expire until 2006. Consumers have Upsher-Smith to thank for this generic competition.

A. The Settlement Cut Schering's Patent By More Than Five Years

Upsher-Smith is a small, family-owned pharmaceutical company based in Plymouth, Minnesota. It has for years marketed potassium in a variety of dosage forms and strengths through its Klor-Con product line. In the early 1990s, Upsher-Smith set its sights on developing a generic version of the leading U.S. potassium chloride product, K-Dur 20. K-Dur 20 is manufactured and sold by Schering, a major international pharmaceutical company approximately one hundred times larger than Upsher-Smith.

After years of research and development, Upsher-Smith in 1995 filed with the FDA an Abbreviated New Drug Application ("ANDA") for a generic alternative to K-Dur 20. Schering promptly sued Upsher-Smith for infringing Schering's '743 patent. The ensuing litigation was intense and hard-fought — even acrimonious — marked by numerous discovery disputes and efforts to disqualify counsel. For Upsher-Smith, the stakes were high, as a Schering victory would bar Upsher-Smith from the market until Schering's patent expired on September 6, 2006. Upsher-Smith hired one of the leading patent law firms in the country and spent more than $

in legal fees — by far its biggest legal expense ever. The cash drain, diversion of executive attention and uncertainty were damaging to Upsher-Smith's business. Yet Upsher-Smith stood toe-to-toe against Schering for eighteen months.

In June 1997, on the eve of trial, Upsher-Smith reached a settlement with Schering under which Upsher-Smith obtained a royalty-free license to sell its generic version of K-Dur 20

beginning September 1, 2001. Thus, through its years of determination and its investment of millions of dollars, Upsher-Smith was able to accelerate generic competition to K-Dur 20 more than five years ahead of the expiration of Schering's patent. This settlement was truly a terrific outcome for Upsher-Smith and consumers. It allowed Upsher-Smith to introduce generic competition five years earlier than it could have if it had lost the lawsuit with Schering and even earlier than it could have if it had won the lawsuit, given the appeal process and the logistics of a small company launching such a major product.

The settlement also left Upsher-Smith free to compete with K-Dur 20 through any existing product in its potassium line — including its Klor-Con 8 and 10 mEq tablets and its Klor-Con 20 powder — or even through any possible new product that did not use the "microencapsulation" process covered by Schering's patent. And Upsher-Smith did indeed compete vigorously with Schering and K-Dur 20 at all relevant times. Typical of this, Upsher-Smith conducted an advertising campaign encouraging substitution of two of its cheaper Klor Con 10 tablets for Schering's larger and harder-to-swallow K-Dur 20 tablets.

Consistent with the settlement, on September 1, 2001 Upsher-Smith began commercial marketing of its generic product, Klor-Con M 20. Klor-Con M 20 sells at a substantial discount to K-Dur 20, and sales have been brisk. In response to Upsher-Smith's introduction of Klor-Con M 20, Schering has introduced its own generic version of K-Dur 20 through its Warrick subsidiary. Upsher-Smith has also licensed its Klor-Con M 20 to an unrelated company, Qualitest, which sells a private-label version of the product competing against Upsher-Smith, Schering and Warrick. Thanks to Upsher-Smith, consumers now have no fewer than three generic alternatives to K-Dur 20 — where previously they had none, and might have had none before 2006.

B. The Complaint Rests Entirely Upon An Alleged "Sham"

Although the Upsher-Smith/Schering settlement introduced generic competition more than five years ahead of the expiration of Schering's patent, the Complaint in this proceeding contends that the settlement was *anti*competitive and unlawful. This contention rests entirely upon the allegation that a licensing agreement between Upsher-Smith and Schering, entered into simultaneously with the patent settlement, was a sham: "The $60 million payment from Schering to Upsher-Smith was unrelated to the value of the products Upsher-Smith licensed to Schering." Cmplt. ¶ 45. The Complaint alleges that the $60 million Schering paid for licenses of Upsher-Smith products were, in reality, disguised payments by Schering to induce Upsher-Smith to "delay" generic competition. Cmplt. ¶ 64. And the Complaint alleges that, but for the payment for delay, Upsher-Smith would not have "agreed to delay its entry for so long." Cmplt. ¶ 64.

Complaint Counsel have candidly acknowledged that to prevail at trial they must prove that the June 1997 licensing transaction was a sham. In open court, Complaint Counsel responded to a question from Your Honor as follows:

> Judge Chappell: I guess I need to ask you one more question. Then are you saying the Government has to prove the payment was for delay in order to win this case?
>
> Complaint Counsel: Absolutely. That's what we will prove at trial. . . .

July 25, 2001 Tr. at 34. Complaint Counsel then argued that the "entire payment" of $60 million was "for delay" rather than for the licensed products. Tr. at 37-38.

The Complaint also alleges that the settlement has the effect of delaying entry of other potential generic competitors, through the operation of the 180-day exclusivity provisions of the Hatch-Waxman Act. According to the Complaint: "By avoiding a court decision that would

have either (a) triggered this 180-day Exclusivity Period (in the event Upsher-Smith prevailed) or (b) resulted in its forfeiture (in the event Schering prevailed), the challenged agreement delays the start of Upsher-Smith's 180-day Exclusivity Period until September 2001 and, as a result, the entry of competition from other generic manufacturers until March 2002." Cmplt. ¶ 66.

On the basis of these allegations, the Complaint asserts two counts against Upsher-Smith, one for unreasonable restraint of trade and one for conspiring with Schering with the "specific intent" to allow Schering to monopolize "the manufacture and sale of potassium chloride supplements approved by the FDA and narrower markets contained therein." Cmplt. ¶¶ 9-10. As relief, the Complaint seeks an order containing various cease-and-desist provisions and requiring Upsher-Smith to relinquish its right to 180-day exclusivity for Klor-Con M 20. Cmplt. ¶¶ 11-12.

C. The Licensing Agreement Was Bona Fide

At trial Upsher-Smith will disprove the Complaint's allegation that the Upsher-Smith/Schering licensing agreement was a sham intended to disguise a payment to delay generic competition. Upsher-Smith will prove that the licensing agreement was a separate, bona fide transaction, and that the six products being licensed — most notably Niacor SR, but the others as well — and Upsher-Smith's production commitments had value in line with the consideration received from Schering. In particular, Upsher-Smith will prove that prior to the Schering transaction it spent well in excess of dollars on R&D for Niacor SR over several years and was committed to recouping that expense by licensing the product outside the United States.

Months before discussing any licensing transaction with Schering, Upsher-Smith retained a U.K. consultant to identify a European licensing partner for Niacor SR, specifically contemplating substantial upfront payments. Upsher-Smith had already undertaken substantive

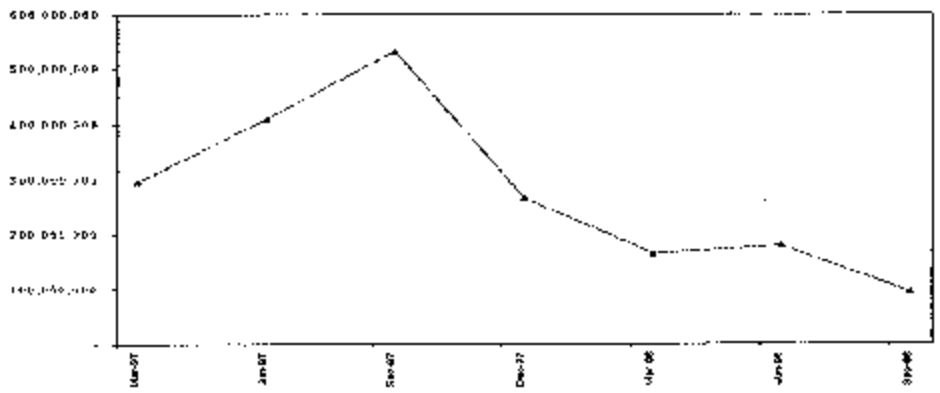
discussions with major pharmaceutical companies about licensing Niacor SR in Europe, at least one of which indicated a willingness to pay substantial upfront payments.

Complaint Counsel appear intent on denigrating the value of Niacor SR and the five other pharmaceutical products licensed to Schering, exaggerating side effects and regulatory hurdles. This strategy will fail. At trial Upsher-Smith will prove — through fact and expert testimony — that the drugs licensed to Schering had substantial value, commensurate with the consideration paid by Schering, and that the terms of the licensing agreement were otherwise reasonable.

Complaint Counsel also appear intent on using 20:20 hindsight to second-guess the consideration paid by Schering. This strategy, too, will fail. A licensing transaction — like any investment — can be fairly assessed only on the basis of the facts and circumstances prevailing at the time that it was formed; many investments may look unwise years later with the benefit of new information and marketplace developments. Upsher-Smith will prove that the drugs it licensed to Schering in June, 1997 had a value reasonably in the range of what Schering agreed to pay at that time.

Evidence of the market value of KOS Pharmaceuticals, for example, provides powerful corroboration of the value of Niacor SR in June 1997. KOS went public in March 1997 essentially as a one-product company. The product was a sustained-release niacin formulation known as Niaspan, which was still awaiting FDA approval in June 1997. On the basis of high hopes for Niaspan, KOS achieved a market value of approximately $400 million by June 1997. *See* Chart below. Both sides negotiating the Upsher-Smith/Schering licensing agreement were well aware of KOS's valuation, and took that into consideration in valuing Niacor SR.

KOS Pharmaceuticals - Market Capitalization



Later in 1997, after the Upsher-Smith/Schering licensing agreement was consummated, KOS's market value plummeted, reflecting disappointing sales of Niaspan. KOS's experience with Niaspan was a significant reason why Schering and Upsher-Smith reconsidered their strategies on Niacor SR in late 1997 and 1998.

The evidence at trial will establish that the licensing transaction was bona fide in all respects. The negotiations were arms-length and consistent with legitimate business conduct; there is no evidence of code-names, secret meetings or other furtive conduct associated with illegal conspiracies. The consideration paid by Schering was commensurate with the products being licensed and the manufacturing obligations Upsher-Smith was assuming. The documentation of the agreement was businesslike and all corporate formalities were followed. As of June 1997, Schering's executives and directors believed that the license and manufacturing agreement was worth more than the present value of the upfront royalty payments (approximately $54 million) and the other consideration paid by Schering. And the parties' post-signing conduct and communications were consistent with their bona fide intentions.

Evidence from the negotiations between Upsher-Smith and Schering will squarely refute the Complaint's allegation that Schering paid for time off the market. The evidence will show that Upsher-Smith and Schering agreed upon the September 1, 2001 entry date well before they negotiated the financial terms of the licensing agreement. There was never any trading of money for delay. Every participant in the negotiations, including Upsher-Smith's outside counsel, will confirm under oath that the licensing transaction was negotiated after the entry date for Upsher-Smith's K-Dur 20 generic had already been established.

At trial Upsher-Smith will also prove that it never conspired to manipulate any "180-day Exclusivity Period." At the time of the June 1997 settlement, FDA regulations did not provide any exclusivity rights to a first ANDA filer who settled its patent-infringement suit with a brand-name company. Upsher-Smith officials believed they would not have any exclusivity upon a settlement with Schering. Exclusivity never came up in settlement discussions with Schering, and the settlement agreement does not allude to, let alone address, any exclusivity rights.

In any event, Upsher-Smith will prove at trial that no other potential generic competitor has been kept off the market by any exclusivity Upsher-Smith possesses. Andrx, the only potential competitor referred to in the Complaint, still does not have tentative approval from the FDA, so it is legally barred from marketing any K-Dur 20 generic notwithstanding any exclusivity that Upsher-Smith possesses. Neither Andrx nor any other company has ever asked Upsher-Smith to waive its exclusivity rights, and those rights will expire at the end of next month. In the meantime, due to Upsher-Smith's aggressive conduct, consumers have no fewer than ***three generic alternatives*** to K-Dur 20 during this so-called "Exclusivity 180-Day Period."

II. THE SETTLEMENT AGREEMENT COMES OUTSIDE THE REACH OF THE ANTITRUST LAWS

The Complaint acknowledges that K-Dur 20 is covered by Schering's '743 patent, expiring on September 5, 2006. Compl. ¶ 34. This patent gives Schering the legal right to exclude all others from the manufacture, use or sale of goods covered by the patent. *See Dawson Chem Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980); *United States v. United Shoe Mach. Co.*, 247 U.S. 32, 57 (1918).

The Supreme Court has carefully delineated boundaries between lawful patent exploitation and antitrust violations. Only agreements that enlarge the scope of a lawful patent monopoly beyond the patent are subject to the Sherman Act. *See United States v. General Elec.*, 272 U.S. 476, 485 (1926) ("But under the patent law the patentee is ***given by statute a monopoly of making, using, and selling the patented article.*** . . . It is only when he adopts a combination with others, by which he ***steps out of the scope of his patent rights*** and seeks to control and restrain those whom he has sold his patented articles in their subsequent disposition of what is theirs, that he comes within the operation of the Anti-Trust Act.") (emphasis added). In *Ethyl Gasoline Corporation v. United States*, 309 U.S. 436 (1940), Chief Justice Harlan Fiske Stone, writing for the Court, articulated the dividing line between the patent law and the Sherman Act:

> The patent law confers on the patentee a limited monopoly, the right or power to exclude all others from manufacturing, using or selling his invention. The extent of that right is limited by the definition of his invention, as its boundaries are marked by the specifications and claims of the patent. He [the patent holder] may grant licenses to ***make, use or vend***, ***restricted*** in point of space or ***time***, ***or with any other restriction upon the exercise of the granted privilege***, save only that by attaching a condition to his license ***he may not enlarge his monopoly*** and thus acquire some other which the [patent] statute and the patent together did not give.

Id. at 456 (citations omitted, emphasis added). This articulation has withstood the test of time. *See, e.g., Brulotte v. Thys Co.*, 379 U.S. 29, 31-32 (1964); *United States v. Masonite*, 316 U.S. 265 (1942); *Carter v. Variflex, Inc.*, 101 F. Supp. 2d 1261, 1265 (C.D. Cal. 2000); *Amgen, Inc. v.*

Chugai Pharm. Co. Ltd., 808 F. Supp. 894, 903 (D. Mass. 1992), *aff'd sub nom., Ortho Pharm. Corp. v. Genetics Institute, Inc.*, 52 F.3d 1026 (1st Cir. 1995); *United States v. CIBA Geigy Corp.*, 508 F. Supp. 1118, 1150-51 (D.N.J. 1976).

At trial the evidence will establish that the Upsher-Smith/Schering settlement agreement gave Upsher-Smith a royalty-free license to market a K-Dur 20 generic more than five years before expiration of Schering's '743 patent. The evidence will also establish that the settlement agreement gives Upsher-Smith unfettered rights to sell its product anywhere in the United States at any price. There will be no evidence that the settlement agreement extended Schering's patent, either by setting Upsher-Smith's entry date after Schering's patent expiration or by the setting the price at which Upsher-Smith's product would be sold. Thus, the evidence will show that the Upsher-Smith/Schering settlement agreement does not fall outside the four corners of Schering's patent and therefore is outside the reach of the antitrust laws.

III. IF THE SETTLEMENT AGREEMENT FALLS OUTSIDE THE PATENT MONOPOLY, IT IS GOVERNED BY THE RULE OF REASON

If the June 17, 1997 Agreement somehow "***enlarges***" the '743 patent monopoly granted to Schering, so as to fall within the scope of the Sherman Act, then the Agreement must be judged under the Rule of Reason.

A. No Basis For *Per Se* Review Of Settlement Agreement Exists

Complaint Counsel argue that the agreement settling the patent litigation between Upsher-Smith and Schering is *per se* illegal under the antitrust laws — this despite a legion of Supreme Court precedents limiting and even disfavoring application of the *per se* rule and scores of cases extolling the procompetitive benefits of patent settlements.

The Supreme Court has made clear that conduct is *per se* illegal under the antitrust laws only when such "conduct [] is ***manifestly anticompetitive***, [] that is, conduct that would always

or almost always tend to restrict competition and decrease output." *Business Elec. Corp. v. Sharp Elec. Corp.*, 485 U.S. 717, 723, 726 (1988) (citations omitted) (emphasis added). Such conduct must have (1) a "***pernicious effect*** on competition" and (2) "***lack*** [] ***any redeeming value*** . . . ." *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 50 (1977) (quoting *Northern Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958)) (emphasis added). The Court has held that the *per se* rule should not apply "to 'restraints imposed in the context of business relationships where the economic impact of certain practices is ***not immediately obvious***." *State Oil v. Khan*, 522 U.S. 3, 10 (1997) (*citing FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 458-59 (1986)) (emphasis added). Thus, the Court has held that conduct is *per se* illegal only if it has "no purpose except stifling of competition." *White Motor Co. v. United States*, 372 U.S. 253, 263 (1963).[1]

In the present case, it is undisputed that as a direct result of the settlement agreement, the life of Schering-Plough's K-Dur 20 patent was cut by more than five years — necessarily increasing competition and increasing output. Respondents' four economic experts — Drs. Addanki, Willig, Ordover and Kerr — have analyzed patent settlement agreements that permit early entry of generic competition to determine their competitive effects and their potential harm

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[1] The Court has severely limited the types of conduct that are *per se* illegal. *See, e.g., United States v. Trenton Potteries Co.*, 273 U.S. 392 (1927) (price-fixing); *United States v. Topco Assocs.*, 405 U.S. 596 (1972) (horizontal market division). In a number of cases, the Court has overturned application of the *per se* rule. *See, e.g., State Oil v. Khan*, 522 U.S. 3 (1997) (overturning *Albrecht*'s *per se* ban on resale price maintenance and substituting the rule of reason); *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Oklahoma*, 468 U.S. 85 (1984) (overturning *per se* rule applied in joint venture case). Courts have even restricted application of the *per se* rule to such traditionally odious practices as boycotts, tying arrangements and even price-fixing. *See, e.g., Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.*, 472 U.S. 284 (1985) (refusing to apply per se rule to boycott aimed at purchasers rather than rivals); *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, (1984) (declaring that *per se* rule applied to tying arrangements only when seller had market power).

to consumers. Based on their analyses, each of these experts concluded that such agreements may be procompetitive.

Furthermore, the Supreme Court has clearly held that the *per se* rule only applies to conduct that ***unambiguous judicial experience*** has demonstrated has no purpose except to foreclose competition. *See State Oil Co.*, 522 U.S. at 10 ("Per se treatment is appropriate '[o]nce experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it.'") (citations omitted). *See also Broadcast Music*, 441 U.S. at 10 (applying rule of reason to price-fixing license because it differed significantly from other price-fixing agreements and because Court had "never examined a practice like this one before"). Thus, business practices with which courts have *not* had "considerable experience" and which have not inevitably resulted in a finding of anticompetitive effects, fall outside the *per se* standard and are subject to a rule of reason analysis. *United States v. Topco Assoc., Inc.*, 405 U.S. 596, 607-08 (1972). In fact, very few business practices have "such predicable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit," that they are ***per se*** illegal, instead *per se* treatment is justified only when "experience with a particular kind of restraint enables the Court to ***predict with confidence*** that the rule of reason will condemn it." *State Oil Co.*, 522 U.S. at 10 (emphasis added) (quoting *Arizona v. Maricopa County Med. Soc'y*, 457 US 332, 342-43 (1982).[2]

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[2] In arguing for *per se* treatment, Complaint Counsel misplace reliance upon cases arising from the Abbott/Geneva and Hoechst/Andrx transactions. *See In re Terazosin Hydrochloride Antitrust Litigation.*, 164 F. Supp.2d 1340 (S.D. Fla. 2000); *In re Cardizem CD Antitrust Litigation.*, 105 F. Supp.2d 682 (E.D. Mich. 2000). But those two transactions took place in different circumstances and were devoid of the procompetitive features that characterize the Schering/Upsher-Smith settlement. Neither settled patent litigation. Neither cut time off a patent. Neither accelerated generic entry. Those transactions also had anticompetitive features not present here, such as contractual commitments not to waive or relinquish 180-day exclusivity rights.

The Supreme Court has never applied the per se standard to an entry-enhancing, patent-shortening patent infringement settlement agreement. No court has considered a patent settlement agreement that has ***reduced*** the life of a patent monopoly. Nor has any court held that such a settlement is "manifestly anticompetitive," by "always or almost always tend[ing] to restrict competition and decrease output." *Business Elec. Corp.*, 485 U.S. at 723. The courts' lack of experience in applying the *per se* rule to entry-enhancing patent settlements militates against a *per se* analysis. Without this "considerable experience" in this area, courts are unable to presumptively determine the anticompetitive effects of patent settlements. *See State Oil Co.*, 522 U.S. at 10.

Finally, public policy favors the settlement of litigation, and in particular the settlement of patent litigation. Courts have noted that "[s]ettlement is of ***particular value*** in patent litigation, the nature of which is often inordinately complex and time consuming." *Arco Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976) (emphasis added). "[S]ettlement agreements should therefore be upheld whenever equitable and policy considerations so permit." *Id. See McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994) ("[c]ompromises of disputed claims are favored by courts"); *Duplan Corp. v. Deering Milliken, Inc.* 540 F.2d 1215, 1222 (4th Cir. 1976) (to declare settlement as an antitrust violation could "unnecessarily place the parties involved in patent litigation in such a position . . . contrary to sound judicial policies which require that settlements be encouraged not discouraged.") Even the FTC and the Department of Justice have declared that patent settlement agreements involving cross-licenses are procompetitive: "Settlements involving the cross-licensing of intellectual property rights can be efficient means to avoid litigation, and in general, courts favor such settlements." Antitrust

Guidelines of the Licensing of Intellectual Property, 5.5 (emphasis added). The universally recognized benefits of patent settlements forecloses any operation of the *per se* standard.

B. Rule of Reason Analysis Vindicates The Settlement Agreement

The rule of reason, "consists of three components: (1) the persons or entities to the agreement ***intend to harm or restrain competition***; (2) an ***actual injury to competition occurs***; and (3) the restraint is ***unreasonable*** as determined by balancing the restraint and any justifications or procompetitive effects of the restraint." *California Dental Ass'n*, 224 F.3d at 947 (quoting *American Ad. Mgmt. v. GTE Corp.*, 92 F.3d 781, 789 (9th Cir. 1996)).[3]

At trial, Upsher-Smith will show that the June 17, 1997 Agreement fostered a number of procompetitive ends: first, cutting more than half of the 110 months then remaining on the '743 patent (June 17, 1997 to September 5, 2006); second, ensuring entry of Upsher-Smith's Klor-Con M20 tablet on a date certain; third, ending the drain of legal fees and executive time in the deadweight loss of litigation; fourth, securing for Upsher-Smith a European marketing partner for six of its pharmaceutical products; fifth, obtaining for Upsher-Smith's owners a needed financial return after years of capital outlay which totaled in excess of $ for just one of the six drugs, Niacor-SR.

A further point bears mentioning. Under the rule of reason, it is not problematic for a settlement agreement to contain ancillary restrictions which prevent the alleged infringer from

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[3] Under the rule of reason, a court must weigh "'all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition.'" *Business Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 723 (1988) (quoting *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977). The factors to consider include: "specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." *State Oil Co.*, 522 U.S. at 10 (citing *Maricopa County*, 457 U.S. at 343 n.13). Moreover, the conduct at issue must be reviewed within the time frame it was adopted — June 17, 1997. *See, e.g., Polk Bros., Inc. v. Forest City of Enters., Inc.*, 776 F.2d 185, 189 (7th Cir. 1985) (a proper rule of reason analysis assesses whether a "restraint ***viewed at the time it was adopted***, may promote the success of . . . more extensive cooperation") (emphasis added).

simply modifying the product thereby eviscerating the purpose of the settlement agreement.[4] The June 17, 1997 Agreement provides: "Upsher-Smith agrees that it will not market in the United States its KLOR CON® M 20 potassium chloride product, ***or any other sustained release microencapsulated potassium chloride tablet***, prior to September 1, 2001." Agreement (emphasis added). This type of language is necessary and standard in settlement agreements, and was merely intended to prevent Upsher-Smith from making a cosmetic or immaterial change to its product and then reintroducing the product claiming it was not the Klor-Con M20 product covered by the settlement agreement. Whatever restraint such language creates — and the evidence will establish that this caused no restraint whatsoever — is entirely ancillary to the overall procompetitive agreement, and furthered a competitive settlement that accelerated Upsher-Smith's entry and shortened Schering's patent by more than five years.[5]

IV. COMPLAINT COUNSEL CANNOT ESTABLISH ANY INTENT OF UPSHER-SMITH TO CONSPIRE TO MAINTAIN SCHERING'S "MONOPOLY"

The Complaint further alleges that Upsher-Smith conspired with Schering to maintain Schering's monopoly. (Count Four). To prove this count Complaint Counsel must demonstrate that Upsher-Smith and Schering acted with specific intent to achieve an unlawful monopoly. *See Great Escape, Inc. v. Union City Body Co., Inc.*, 791 F.2d 532, 540-41 (7th Cir. 1986); *In re Kellog Co.*, 99 F.T.C. 8 (1982). One is said to have acted with "specific intent" if one

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[4] As the court explained in *Rothery Storage & Van Co. v. Atlas Van Lines*, 792 F.2d 210, 224 (D.C. Cir. 1986): "To be ancillary, and hence exempt from the *per se* rule, an agreement eliminating competition must be subordinate and collateral to a separate, legitimate transaction." *See also United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 282 (6th Cir. 1898).

[5] Even Complaint Counsel's industrial organization expert, Dr. Bresnahan, acknowledged: " " Bresnahan Dep. at . Nor could Complaint Counsel's expert . *See* Bresnahan Dep. at 108-09 (Dr. Bresnahan).

"consciously desired" the result prohibited by law. *See United States v. Gracidas-Ulibarry*, 231 F.3d 1188, 1196 (9th Cir. 2000) (*en banc*) (citations omitted). Thus, to establish specific intent, Complaint Counsel must prove that Upsher-Smith "***consciously desired***" that Schering monopolize the relevant market.[6] The evidence will show Upsher-Smith had no such intent.

As a matter of law, however, Upsher-Smith could not have possessed the specific intent required for conspiracy to monopolize. It is well established that a defendant cannot specifically intend to violate a law when that law is unsettled or subject to multiple interpretations. *See United States v. Critzer*, 498 F.2d 1160, 1162 (4th Cir. 1974) ("when the law is vague or highly debatable, a defendant — actually or imputedly — lacks the requisite intent to violate it"). The Supreme Court, and numerous other courts, have reversed convictions and vacated civil penalties on the grounds that the uncertainty of the law negated the element of specific intent. *See, e.g., James v. United States*, 366 U.S. 213 (1961) (reversing conviction for tax evasion for lack of specific intent because the taxability of embezzled funds was uncertain). In the present matter — a case of first impression, where the legality of Upsher-Smith's conduct "was hitherto untested by any sort of tribunal" — Upsher-Smith could not, as a matter of law, have possessed the requisite specific intent. *See AFL-CIO v. Federal Election Comm'n*, 628 F.2d 97, 101 (D.C. Cir. 1980).

Even if Complaint Counsel could as a matter of law show specific intent on Upsher-Smith's part, they would then face the factually impossible hurdle of demonstrating that Upsher-Smith's ***specific purpose*** in signing the June 17, 1997 agreement was to maintain Schering's

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[6] *See SuperTurf, Inc. v. Monsanto Co.*, 660 F.2d 1275, 1283 (8th Cir. 1981) (rejecting conspiracy to monopolize claim where plaintiff failed to prove that alleged co-conspirators shared alleged monopolist's "specific intent to create a monopoly for [itself]").

monopoly in the potassium chloride supplements market.[7] Upsher-Smith's continued sales of competing potassium chloride products like Klor-Con 10 — products that compete vigorously with Schering's K-Dur 20 product — and its expensive defense of the patent infringement case demonstrate the implausibility of this claim. *See TV Communications Network, Inc. v. Turner Network Television, Inc.*, 964 F.2d 1022, 1026-27 (10th Cir. 1992) (no specific intent to conspire where such a conspiracy would be contrary to the interests of that defendant). Upsher-Smith was motivated by the desire to sell its products to Schering's detriment, not to maintain Schering's lawful patent monopoly.[8]

Similarly, Complaint Counsel cannot establish that Upsher-Smith intended to use the Hatch-Waxman "180-day Exclusivity Period" to further the alleged conspiracy for Schering to monopolize the potassium chloride supplement market. Upsher-Smith was not entitled to 180-day exclusivity at the time it negotiated and concluded the settlement agreement — thus, any subsequent exclusivity Upsher-Smith obtained as a result of a change in the law cannot be considered an unreasonable restraint. As Complaint Counsel admits, the "successful defense" requirement was the law of the land until 1998, when two circuit courts held it unlawful, *see Mova* and *Granutec*, and the FDA revoked the requirement in June 1998. *See* Hoffman Rep. at

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[7] *See In re Microsoft Corp. Antitrust Litig.*, 127 F. Supp. 2d 728, 731 (D. Md. 2001) (specific intent "signifies something more than willing, voluntary, and knowing participation in the illegal course of conduct that [defendant] is alleged to have pursued. It means participating in that course of conduct for the specific, shared purpose of maintaining [defendant's] monopolies."); *see also Rebel Oil Co., Inc. v. Atlantic Richfield Co.*, 51 F.3d 1421, 1437 n.8 (9th Cir. 1995) ("To prove a conspiracy to monopolize, Rebel must show that the independent dealers had the specific intent to conspire to monopolize; it is not enough to show that the dealers merely agreed to go along with ARCO's pricing.").

[8] It is Complaint Counsel's burden to prove the relevant product market. Upsher-Smith will show at trial that the relevant antitrust product market is at least the sale and manufacture of all potassium supplements. Compl. at 4. The evidence will show that other potassium chloride products that compete in the potassium chloride market include at least: K-Tab, Micro-K, K-Lyte, K-Lor, Slow-K, Koachlor-SF and Upsher-Smith's portfolio of Klor-Con products.

[redacted] As a result of this change in the law — almost one year after the settlement agreement — the FDA subsequently determined in November of 1998 that Upsher-Smith was entitled to 180-day exclusivity. At the time of the settlement, Upsher-Smith had no notion that these future events would afford it 180-day exclusivity. Thus, it was a legal impossibility for Upsher-Smith to have acted with any intent, much less specific intent, to harm competition via the 180-days.[9]

V. THE COMPLAINT'S REQUESTED RELIEF IS MOOT

As if to demonstrate its procompetitive nature, the June 17, 1997 settlement agreement by its own force has already accomplished what the Complaint prays for: Upsher-Smith's generic entry. That entry occurred September 1, 2001, thereby rendering this case moot. Once an allegedly illegal conduct has discontinued, the party bringing an action has a duty to show that "there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); *see also Borg-Warner Corp. v. FTC*, 746 F.2d 108, 110-11 (2d Cir. 1984) (reversing and dismissing Commission order because company was no longer infringing by the time the Commission issued its order, and the FTC staff failed to prove: "a 'cognizable danger of recurrent violation' in this case."). In this case, Complaint Counsel can adduce no evidence that Upsher-Smith will in the future enter into any agreement like the June 17, 1997 Agreement — which is a singular failure given that Complaint Counsel has long known that the trial would proceed after Upsher-Smith introduced its Klor-Con M20 product. In short, as in *Borg-Warner*, the issues raised by Complaint Counsel are moot and "no order [is] warranted." *Id.* at 109.

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[9] To the extent the law was so unsettled and unclear, Complaint Counsel cannot establish that Upsher-Smith had the intent required under Counts 1 or 4. As noted above, it is well established that a defendant cannot possess the specific intent to violate a law when that law is vague and highly debatable. *See, e.g., James*, 366 U.S. at 221 (reversing conviction for tax evasion despite finding defendant's actions violated the tax laws because defendant did not possess "specific intent" to violate the tax code where the taxability of embezzled funds was uncertain).

CONCLUSION

Through substantial effort Upsher-Smith won the right to introduce generic competition to K-Dur 20 more than five years ahead of the expiration of Schering's '743 patent. As a result, today there are no fewer than three generic competitors on the market. Upsher-Smith should be praised for bringing about this procompetitive result, not falsely accused of violating the antitrust laws.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 16, 2002 I caused a paper original and one copy as well as an electronic version of the foregoing Upsher-Smith's Trial Brief to be filed with the Secretary of the Commission and two paper copies to be provided by hand delivery to:

Hon. D. Michael Chappell
Administrative Law Judge
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