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 REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS DUE TO COMPLAINT COUNSEL'S FAILURE TO ESTABLISH A PRIMA FACIE CASE

Complaint Counsel's opposition brief is a striking abandonment of the case filed on March 30, 2001. For example:

(1) Before trial, Complaint Counsel maintained that the licensing agreement between Schering and Upsher-Smith was a sham. In fact, at the Pretrial Hearing, Complaint Counsel went so far as to declare: "The ***entire payment*** was for delay." Hrg. July 25, 2001 at 38 (emphasis added). Now, however, having failed to prove a sham transaction at trial and having heard the testimony of their witnesses, Complaint Counsel state: "We do not contend that the Upsher-Smith products that were licensed had no value." Opp. at 6.

(2) Complaint Counsel make no attempt to defend the valuation testimony presented in the case in chief. In their case in chief, Complaint Counsel failed to prove that the value of the six product licenses and six manufacturing agreements in the June 1997 Agreement were worth less than $54.5 million. Dr. Nelson Levy's testimony, even if fully credited, does not establish

the value of these twelve components as of June 1997, as Professor Timothy Bresnahan testified must be done. Tr. 659:17 – 661:13 (all prongs of Bresnahan test are evaluated as of June 1997). And Dr. Levy's use of $60 million for his testimony about Niacor SR (Tr. 2133:17-2134:8), one of the twelve licenses, fails to use Professor Bresnahan's $54.5 million yardstick — the value of the three upfront payments in June 1997. Tr. 662:22-663:5 (Bresnahan conceding that the June 1997 value of the three payments to Upsher-Smith was $54.5 million).[1] In other words, there was no proof at all in Complaint Counsel's case in chief of a "reverse payment."

(3) In their Trial Brief, Complaint Counsel asserted that Schering had monopoly power in the relevant market. Trial Br. at 61-65. In response to a direct question from Your Honor, Professor Bresnahan stated unequivocally that the relevant product market was "20 mEq. sustained release potassium chloride tablets and caplets," (Tr. 1282:20-24) — *i.e.*, K-Dur 20. Professor Bresnahan also testified that Schering had to be a "monopolist" as of June 1997 for his test to be met (Tr. 659:11-20). But in their Opposition, aware that they based their case in chief on an improperly gerrymandered product market consisting only of K-Dur 20, and in the face of ***uncontroverted*** evidence that Schering possessed less than 40 percent of the "crowded" potassium supplement market in June 1997, Complaint Counsel assert that they need not prove that Schering was a monopolist in June 1997, only that Schering possessed "market power."[2] Complaint Counsel's self-serving shift cannot save their case from dismissal.

(4) Similarly, in an astonishing admission, Complaint Counsel abandon any pretense of attempting to define a K-Dur 20-only relevant product market. Complaint Counsel had to

[1] Professor Bresnahan testified that each of the six product licenses and six manufacturing supply agreements conferred on Schering positive value as of June 1997. *See* Mot. at 25 (collecting record citations).

[2] *See* Opp. at 8 n.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

abandon the assertions made in the Trial Brief (at 63) that K-Dur 20 "has clear therapeutic advantages over other supplements" in the face of Complaint Counsel's own witnesses, Messrs. Goldberg and Teagarden, who testified that all potassium supplements are "therapeutically equivalent." See, e.g., Tr. at 144:15-21 (United Healthcare's Goldberg). Thus, Complaint Counsel now concede that there are many therapeutically equivalent products: "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." Opp. at 13. Instead, unlike thousands of antitrust plaintiffs before them, and unlike the Commission itself in cases such as *Staples*, *Cardinal Health*, *Olin*, and *Coca-Cola*, Complaint Counsel abandon their attempt to establish a narrow product market under the *Brown Shoe* indicia. Indeed, Complaint Counsel now eschew the very exercise of defining a relevant product market. Instead, Complaint Counsel seek to show "direct evidence" of the alleged "market power" of Schering through "output reduction" and "supracompetitive pricing" – a bold and difficult endeavor not accomplished in this case. *See supra* at 10-13.

(5) Complaint Counsel's Opposition wholly fails to address the claim that Schering and Upsher-Smith somehow "manipulated" the 180-day Hatch-Waxman exclusivity period to prevent other generic applications from being approved. Instead, the case in chief established through expert Joel Hoffman that he would have had "no idea" what the effect of the Agreement would have been as of June 1997 on the 180-day provision and that the 180-day provision would apply to any of the possible litigation or settlement outcomes -- win, lose, or draw for Upsher-Smith. Mot. at 35.

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interchangeably;" but "[w]e note, however, that as a matter of law, market power is considered less substantial than monopoly power, thus requiring a lower threshold of proof").

(6) Finally, Complaint Counsel abandon their argument that the "any other sustained release" tablet language of Paragraph 3 of the June 1997 agreement restricted competition. Mot. at 37-39.

Complaint Counsel's Opposition is remarkable for the amount of time spent attempting to dodge its burden of proof and for the paucity of factual proof actually established in the case in the chief. Complaint Counsel's failure of proof not only justifies dismissal of the Complaint — it compels it.

I. COMPLAINT COUNSEL HAVE FAILED TO ESTABLISH A PRIMA FACIE CASE UNDER COUNT I OF THE COMPLAINT

Count One of the Complaint charges that the agreement between Upsher-Smith and Schering "unreasonably restrains commerce, and is therefore an unfair method of competition." Compl. ¶ 68. Notwithstanding the suggestion of Complaint Counsel to the contrary, there can be no dispute that Complaint Counsel bear the burden of proving their case. *See, e.g., California Dental Ass'n v. FTC*, 224 F.3d 942, 957 (9th Cir. 2000) (on remand from the Supreme Court) (holding that the FTC had not met its burden of proving the "net harm to competition" under the full rule of reason analysis). Moreover, the Supreme Court has made clear that under the rule of reason — the test applicable to this case[3] — the party bringing an action must demonstrate that the restraint alleged actually harms competition. *See, e.g., California Dental Ass'n v. FTC*, 526 U.S. 756, 771 (1999); *Standard Oil Co. v. United States*, 283 U.S. 163, 1979 (1931). *See also Seagood Trading Corp. v. Jerrico, Inc.*, 924 F.2d 1555, 1569-70 (11th Cir. 1991); *United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993); *Consol. Metal Prods., Inc. v. Am. Petroleum*

[3] Given the novelty of the "restraint" alleged by Complaint Counsel, the rule of reason applies. *See* Mot. at 27-28 (collecting authorities); Tr. at 156:15-16 ("This is a case of first impression. . . . I find no Commission precedent in the area.") (Chappell, J.). Complaint Counsel still have failed to present any evidence that the alleged restraint actually harmed competition, e.g., Complaint Counsel have not proved that another settlement with an earlier date than September 1, 2001 was possible or that the results under litigation would have been better than the settlement.

Inst., 846 F.2d 284, 292 (5th Cir. 1988); *Cowley v. Braden Indus.*, 613 F.2d 751, 755 (9th Cir. 1980).[4]

A. Complaint Counsel Have Failed To Prove That (1) There was a Reverse Payment or (2)There Was A Payment For Delay

1. No "Reverse Payment" Was Established At All

Complaint Counsel have not proven that a reverse payment was made in this case. Professor Bresnahan testified that (1) the "reverse payment" issue — Prong Three of his test — must be evaluated as of June 1997 (Tr. 659:17-661:13); (2) the three upfront payments had a net present value of $54 million (Tr. 662:22-663:5); and (3) that each of the six product licenses and each of the six supply agreements (see CX 348 at Paras. 7 – 10) had a positive value as of June 1997. (Tr. 655:15-656:6). These concessions made it imperative that Dr. Levy, Complaint Counsel's sole valuation expert, would testify to the overall value of the six product licenses and six supply agreements that Upsher-Smith granted to Schering-Plough as exceeding $54 million.

Dr. Levy refused to do so. He only testified as to the value of the Niacor SR license, and he ignored the other five product licenses. Tr. 2064:1-25, 2057:25-2058:2; see also Mot. at 23-25. Compounding this failure of proof, he used the nominal value of the payments, $60 million, rather than the economic value of the payments of $54 million. Tr. 2133:17-2134:8. And he conducted no evaluation of Niacor SR — he cannot say how much the Niacor SR license was worth as of June 1997 at all. Levy simply opined that he felt $60 million was too much for Niacor SR. Tr. 1306:18-1307:21. Quite apart from the grounds stated in Respondents' motion in limine, even if his testimony is fully credited, his testimony as a logical matter simply fails to analyze, much less evaluate, 11 of the 12 items of consideration granted by Upsher-Smith to

[4] As Complaint Counsel concede, once the complainant has established anticompetitive effect, then, and only then, does the burden shift to the respondent to show procompetitive justifications. *See* Opp. at 7.

Schering Plough. The failure to prove a reverse payment alone warrants dismissal of Complaint Counsel's case at the close of the case in chief.

Faced with this abject failure of proof, Complaint Counsel now assert that "***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." Opp. at 6 (emphasis added). That is precisely what Complaint Counsel must do here. But by failing to value all of the licenses conveyed in June 1997, there is simply no evidence of a "reverse payment." This is particularly true where, as here, the Schering Board ascribed real positive value to each of these licenses in June 1997 that was many times greater than the $54 million net present value of the three upfront payments. See CX 338 at SP 12 00275 (Schering Board June 1997 valuation: Niacor SR economic value alone was $225 - $265 million).

2. Complaint Counsel Failed to Prove Any Payment for Delay

First, Complaint Counsel's own expert economist, Professor Bresnahan, admitted several times that the June 1997 agreement has procompetitive elements, e.g., valid joint venture to market Upsher-Smith's products overseas where the firm had no sales office or presence. *See e.g.*, Tr. 666:25, 667:1-4, 906:9-15, 963:20-25, 964:1-7. Second, the face of the agreement is not unambiguously anticompetitive. Without extrinsic proof of a lack of value in the six product licenses and six supply agreements, it is impossible to discern an anticompetitive effect. Moreover, there is no way to conclude that an agreement that cuts more than five years off the life of a patent is anticompetitive on its face.

The assertion that "There is no dispute that under the challenged agreement . . . Upsher-Smith agreed not to launch any ***competing product*** for over four years" (Opp. at 3) is simply false. There was a real dispute about this, and Respondent's response was not answered by

Complaint Counsel. Upsher-Smith's motion to dismiss specifically addressed the "other tablet" language of Paragraph 3 of the June 1997 Agreement (Mot. at 37-39), evidence that was met with silence by Complaint Counsel. Moreover, the "other tablet" language of Paragraph 3 specifically permitted Upsher-Smith to continue to market a whole host of competing products including powders, effervescents and various wax-matrix tablets. See, e.g., Tr. 232:6-234:10 (Teagarden); Tr. 144:22-146:17 (Goldberg); Mot. at 7-9, 20-23.

Third, Complaint Counsel cling to the narrow thread that the lead-in language in Paragraph 11 somehow establishes that there was a payment for delay. The lead-in language in Paragraph 11 is far from proof of any payment for delay on the face of the agreement.[5] Indeed, the agreement makes clear that the three upfront payments are "royalty payments," CX 348 ¶ 11(i)-(iii), which are presumptively for the licenses. *See Sierra Club Inc. v. C.I.R.*, 86 F.3d 1526, 1531 (9th Cir. 1996) ("'royalty' commonly refers to a payment made to the owner of property for permitting another to use the property") (citing *Black's Law Dictionary* 1330-31 (6th ed. 1979)).[6]

[5] Complaint Counsel incorrectly assert that Schering's three upfront royalty payments were non-contingent. Under the governing law of New Jersey, (*see* CX 348 at Para. IV, New Jersey law governs), the Agreement contained, *inter alia*, the constructive condition that Upsher-Smith would perform all of its obligations to Schering without material breach. *See R.J. Gaydos Ins. Agency, Inc. v. Nat'l Consumer Ins. Co.*, 168 N.J. 255, 276 (2001) (as a general rule, "every contract in New Jersey contains an implied covenant of good faith and fair dealing"); *Palisades Props., Inc. v. Brunetti*, 44 N.J. 117, 130 (1965) (where good faith and fair dealing make it apparent that certain conditions are necessarily involved in the contract, New Jersey courts impose constructive conditions to accomplish such a result). Had Upsher-Smith materially breached its implied obligations under the contract and Schering would have had grounds to withhold any subsequent payments. *Aronsohn v. Mandara*, 98 N.J. 92, 100 (1984) (constructive conditions are as effective as those expressed, and the non-fulfillment of a required condition can result in a material breach of the contract); *McGarry v. Saint Anthony*, 307 N.J. Super. 525, 533 (1998) (where employee breached an implied condition of the contract, he was not entitled to recover termination pay); *Lo Re v. Tel-Air Communications, Inc.*, 200 N.J. Super. 59, 69-71 (1985) (a party may withhold payment in anticipation of breach). Therefore, Schering's royalty payments were not in fact "non-contingent," as Complaint Counsel assert.

[6] Furthermore, Paragraph 11's references to the licenses include an explicit reference to the "SP Licensee" which term is not defined until the four license paragraphs, paragraphs 7 to 10. CX 348 at Exh. A at USL 03187-88.

Finally, because Complaint Counsel have entirely abandoned their theory that the agreement was a sham, they necessarily are asking this Court to second-guess what must be a bona fide agreement between Upsher-Smith and Schering — a role as to which any court is ill-suited. Your Honor has not been presented with sufficient valuation information from which an inference could be drawn that the six product licenses and six supply agreements did not confer $54.5 million in value to Schering in June 1997. Dr. Levy admitted under oath that he did not employ the $54.5 million yardstick of Dr. Bresnahan and did not attempt any assessment of five of the product licenses. See Mot. at 24-25 (collecting references to Levy and Bresnahan testimony concerning valuation). Complaint Counsel's silence is deafening on this point. Unable to establish a reverse payment, the case is hopelessly unproven.

B. Complaint Counsel Failed To Prove Its K-Dur 20-Only Product Market and Failed to Prove Injurious Exercise of Market Power as of June 1997

As a threshold matter, there can be no dispute about the relevant period in which to measure market share or market power. It is June 1997, as Professor Bresnahan conceded in cross-examination. Tr. 659:17-66:13.

1. Single-Product Product Markets Are Disfavored

None of the cases Complaint Counsel cite overcome the overwhelming weight of authority against finding a single-product product market consisting of only K-Dur 20. *See* Mot. at 21. Complaint Counsel's reliance on *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1063 (3d Cir. 1978), cited at Opp. 19-20, is misplaced because the decision supports classic *Brown Shoe* analysis. In *SmithKline*, the Third Circuit defined a separate product market for the family of cephalosporin antibiotics based on the fact that cephalosporin antibiotics were not therapeutically interchangeable with other antibiotics: cephalosporins were broader than other antibiotics, and served a distinct group of patients who were penicillin-allergic. *Id.* at 1062-65.

Here, the case in chief of Complaint Counsel established precisely the opposite: other potassium products such as other tablet dosages, powders, effervescents and liquids were "therapeutically equivalent" with K-Dur 20. Tr. 144:15-21 (Goldberg testifying that all of the potassium products listed in United Healthcare formulary were therapeutically interchangeable; discussing USX 277, Preferred Drug List).

Similarly, the remaining cases cited by Complaint Counsel do not establish single-product product markets; instead, courts applied *Brown Shoe* practical indicia to find broader submarkets. *See FTC v. Cardinal Health, Inc.*, 12 F.Supp.2d 34, 45-50, 52 (D.D.C. 1998)(more than 4 major national drug wholesalers); *FTC v. Staples, Inc.*, 970 F.Supp. 1066, 1074-78 (D.D.C. 1997) (3 office superstore chains, applying *Brown Shoe* indicia); *In the Matter of Coca-Cola Bottling Co. of the Southwest*, 118 F.T.C. 452, 538-42, 553-74 (1994) (3 major branded soft-drink bottlers; applying *Brown Shoe* indicia); *In the Matter of the Olin Corp.*, 113 F.T.C. 400, 449-50, 452-579, 595-600 (1994) (Commission affirming ALJ's use of *Brown Shoe* factors; 3 firms in dry pool sanitizer market). And application of these familiar *Brown Shoe* indicia simply will not support a submarket consisting of only K-Dur 20 here. *See* Mot. at 9-17. In fact, Complaint Counsel largely concede that the product market for potassium supplementation for hypokalemics is broad: "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')." Opp. at 19 (emphasis added). And Complaint Counsel did not respond to the examination of the record in light of *Brown Shoe* indicia. Mot. at 10-14.

2. Complaint Counsel Failed to Establish Market Share in Excess of 40% as of June 1997

Complaint Counsel have no response to the fact that K-Dur 20 never exceeded 40%

market share in terms of TRX — total prescriptions — prior to June 1997, the relevant date for assessing the market power of Schering-Plough. *See* Tr. 659:17-661:13 (Bresnahan -- prong one -- measured as of June 1997). As a matter of law, a market share less than 40% will lead to a finding that the defendant lacked market power in the relevant market under the Rule of Reason. *See* cases cited in Mot. at 18 and n.10 (collecting cases).

3. Complaint Counsel Failed to Establish "Market Power" by Failing To Prove "Direct Evidence" of Market Power of Schering in June 1997

Having failed to present a defensible relevant product market case, Complaint Counsel cling to the narrow holding of *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 461 (1986), Opp. at 9, and dicta from *Rebel Oil Co., Inc. v. Atlantic Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995), that a plaintiff may be able to establish market power through "evidence of restricted output ***and*** supracompetitive prices." Opp. at 9 (emphasis added). They do this despite the fact that their economic expert began his analysis with the classic approach of defining a relevant product market. Complaint Counsel through its expert Professor Bresnahan asserted a 20 mEq tablet and capsule product market (1) in his expert report (CX 751 at 26); (2) in the direct examination of Professor Bresnahan (Tr. 495:19-25); and (3) so testified in direct response to a question from Your Honor. (Tr. 1282:20-24).

Complaint Counsel's abandonment of Professor Bresnahan's definition of the relevant product market and hasty retreat to *Indiana Federation* cannot salvage their case. In that case, the Supreme Court considered a boycott by members of the Indiana Federation of Dentists who agreed collectively to refuse to submit x-ray data to insurance companies in order to thwart the review of their dental care decisions. 476 U.S. 447, 448-52. Unlike the present case, the Commission had presented competent evidence of the relevant product market and market shares, and the Court relied on evidence of market shares of 67% and 100% in considering the

effect of the restraint on two Indiana towns. 476 U.S. at 451. The Court expressly observed that the dentist members of the Federation "were highly concentrated in and around three Indiana communities . . . The Federation succeeded in enlisting nearly ***100% of the dental specialists in the Anderson area***, and approximately ***67% of the dentists in and around Lafayette.***" 476 U.S. at 451 (emphasis added). The Court relied on the Commission's finding "that in two localities in the State of Indiana (the Anderson and Lafayette areas), Federation dentists ***constituted heavy majorities*** of the practicing dentists and that as a result of the efforts of the Federation, insurers in those areas were, over a period of years, actually unable to obtain compliance with their requests for submission of x rays." 476 U.S. at 460 (emphasis added). The Supreme Court concluded "the finding of actual, sustained adverse effects on competition ***in those areas where IFD dentists predominated***, viewed in light of the reality that markets for dental services tend to be relatively localized, is legally sufficient . . . ." *Id.* at 461 (emphasis added).[7]

Just as Complaint Counsel misplace reliance on *Indiana Federation*, they also misplace reliance on *Rebel Oil*. In *Rebel Oil*, the Seventh Circuit in dicta noted that "the injurious exercise of market power" may be established with evidence of "restricted output and supracompetitive prices." 51 F.3d at 1434. The Seventh Circuit went on to evaluate in that case the proposed product market asserted by plaintiff, observing: "Market definition is critical. With a definition of the relevant market, it is impossible to determine market share." *Id.* at 1434. The Seventh Circuit rejected the plaintiff's narrow product market of full-serve sales of gasoline as a distinct product market from all sales of gasoline. *Id.* at 1436. Further, the Court found no

[7] Furthermore, the boycott of insurance companies was a restraint for which "no elaborate industry analysis is required to demonstrate the anticompetitive character of such an agreement," *id*. at 459, unlike the restraint at issue here which Complaint Counsel admit has procompetitive features according to Professor Bresnahan. Finally, the Supreme Court rejected the more extreme position advanced by the Commission that the Federation's conduct "can be condemned regardless of market power or actual effect" because they represent a continuation of restraints by a predecessor organization. *See id*. at 461 n.3

genuine issue as to market power given the ability of rivals to expand output, *id.*,. at 1442-43 (discussing attempted monopolization claim), and dismissed claims brought under Sections 1 and 2 of the Sherman Act. *Id.* at 1448.

Here, Complaint Counsel failed to prove either one of these two requirements: "evidence of restricted output ***and*** supracompetitive prices." First, Complaint Counsel failed to adduce any evidence of restricted output by Schering. To the contrary, the evidence presented during Complaint Counsel's case in chief showed that Schering consistently was ***expanding — not restricting — output*** of K-Dur 20. *See, e.g.*, CX 20 at SP 4035 (K-DUR TRX's up "9%" Year to Date April 1997 vs. Year to Date April 1996; and new prescriptions, NRX, "up 8%" for K-DUR in that same period); Tr. 820:16-19; 821:18-24; 822:18-20 (Bresnahan conceding that Schering did not decrease output but rather increased output of K-Dur 20 over the relevant time period).

Complaint Counsel adduced no evidence of supracompetitive pricing of K-Dur 20 as of June 1997 through Professor Bresnahan, because: (1) he had no data set for Schering's prices (Mot. at 6); (2) he had no data set for competitors' pricing to compare the Schering K-Dur 20 pricing (*Id.*); (3) he conducted no econometric study of pricing or demand, Tr. 685:18 – 686:9, so he had no basis for controlling for other variables; (4) testimony — including customer testimony — elicited during Complaint Counsel's case established that other potassium products competed in price against K-Dur 20. *See* Tr. 224:17 – 19; 215:22-24; 218:2-6 (Mr. Teagarden conceding that other potassium chloride supplements had same relative price as K-Dur 20); Tr. 730:8-13 (Bresnahan admitting that other branded potassium products had "comparable" prices to K-Dur 20); (5) Bresnahan did not study Schering's costs, *see, e.g.*, Tr. 811:24-812:5; thus, he could not know whether the prices Schering charged were above market prices; (6) he made no

study of promotional expenses, so he could not distinguish the role of advertising in costs (Tr. 877:10-22); (7) he made no study of rebates, which reduce the net price that customers pay (Tr. 702:1-20); (8) he conceded that other brands of potassium were comparably priced (Mot. at 12); and (9) the pricing differences that did exist were leading to substitution of Upsher-Smith's wax matrix sales and generic potassium sales. Mot. at 7-8.[8]

4. Complaint Counsel Confuse Mandatory Substitution Laws with "Direct Evidence of Market Power"

Complaint Counsel rely on evidence of projections, generic pharmaceutical theory, and recent sales data to argue that the branded firm's sales decline after the introduction of an AB-rated generic substitute ***demonstrates*** "monopoly power" of Schering's K-Dur 20. Opp. at 10-18. In fact, such evidence only ***demonstrates the compliance with mandatory state substitution laws***. When an AB-rated generic becomes available, in some states by force of law only the AB-rated generic can be supplied. See Opp. at 17-18 and nn.46, 47. Indeed, a significant part of the shift in sales resulted from mandatory state laws that ***compel*** pharmacists to switch from K-Dur 20 to the AB-rated substitute, regardless of prescription — a phenomenon conceded by Complaint Counsel:

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[8] Complaint Counsel take no consistent position on market definition or power. For the period spanning 1995 to September 1, 2001, Complaint Counsel stress a price difference between K-Dur 20 and other potassium products created a separate product market for K-Dur 20 (*i.e.*, that this single potassium supplement constituted its own product market). *See* Opp. at 13-14 (quoting CX 18, a single Schering marketing document); 432:1-433:9, 475:3-484:19 (Bresnahan testifying as to pricing difference). For the period ***after September 1, 2001***, Complaint Counsel jettison their pricing canard and stress unit sales data in an effort to demonstrate that Klor-Con M 20 competes with K-Dur 20. Opp. at 10-20. This shift is not accidental: Complaint Counsel are aware of the record evidence that the entry of an AB-rated generic does not lower the price of the branded product. Tr. 1194:24 – 1195:14 (Bresnahan conceding that "when a low-priced generic enters the market, generally speaking, it does not cause the brand name product to lower its pricing"). This shift also conveniently ignores pre-September 1, 2001 evidence of the shift in sales away from K-Dur 20 that occurred due to a pricing difference against certain generic potassium, that Dr. Bresnahan acknowledge. Mot. at 6-10, 15-16 (collecting record citations to Bresnahan testimony). Complaint Counsel also ignore the role that brands, advertising and detailing play in creating a premium image for K-Dur 20 – an entirely lawful conduct of Schering. Mot. at 17-23. Complaint Counsel ignore the price effects after September 1, 2001 because they were unable to establish that the price of K-Dur 20 went down as a result of the marketing of Klor Con M20.

> 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***.

Opp. at 17 (emphasis added). This situation, however, does not describe an environment of free-market competition, but the opposite: the force of government intervention. State substitution laws simply ban or severely constrain the ability of branded drug producers to compete with their AB-rated generic competitors. K-Dur 20 does not compete on a level playing field under such laws. A state law that shifts sales away from a product will do so regardless of whether that product has "market power" or "monopoly power" in the sense described by the nation's antitrust laws.

C. Complaint Counsel Have Failed To Satisfy The Rule of Reason

As detailed in Upsher-Smith's moving papers, Complaint Counsel failed to present sufficient evidence to satisfy the three-part rule of reason analysis. First, Complaint Counsel failed to demonstrate that the Agreement had an anticompetitive effect on competition, a threshold showing under the Rule of Reason. *See California Dental Ass'n v. FTC*, 224 F.3d 942, 947 (9th Cir. 2000) (on remand from U.S. Supreme Court) (proof of "injury to competition" is an essential element of a rule of reason analysis). Indeed, it is undeniable that because of the Settlement Agreement, consumers were assured of the introduction of a generic to K-Dur 20 ***more than five years*** before expiration of Schering's patent -- this certain benefit to consumers could not have been assured in the fog of the patent litigation. Complaint Counsel's failure to adduce evidence that the patent-busting Settlement Agreement was anticompetitive is fatal to their case.

Finally, as discussed in Upsher-Smith's moving papers, Complaint Counsel's case in chief must be dismissed because they failed to demonstrate any ***net*** anticompetitive effect at all as required under the rule of reason analysis. *See* Mot. at 27-28, 31; *see also California Dental Ass'n v. FTC*, 526 U.S. 756, 781 (1999) ("the Court of Appeals did not scrutinize the assumption of relative anticompetitive tendencies"); *id.* at 774 ("it does not obviously follow that such . . . [practices] would have a net anticompetitive effect here."); *Continental Airlines, Inc. v. United Airlines Inc.*, 277 F.3d 499, 508 (4th Cir. 2002) ("a plaintiff must show that the net effect of a challenged restraint is harmful to competition"); *Seagood Trading Corp*, 924 F.2d at 1569 (under the rule of reason, "[t]he burden of proving . . . an unjustified anticompetitive effect is on the plaintiffs"). In fact, in Complaint Counsel's case in chief, Bresnahan acknowledged that the June 1997 agreement had ***procompetitive*** effects. *See* Tr. 906:9-21; 963:20-25; 964:1-7; 986:9-18. Such failure of proof requires a dismissal of the Complaint.

II. COMPLAINT COUNSEL'S OPPOSITION EXPOSES THE FAILURE TO ESTABLISH UPSHER'S SPECIFIC INTENT TO CONSPIRE TO FURTHER AN ALLEGED SCHERING MONOPOLY

Count IV of the Complaint alleges that Upsher-Smith and Schering conspired to monopolize with specific intent. Yet in their case in chief, Complaint Counsel failed to establish that Upsher-Smith possessed a specific intent to monopolize — the key element of the conspiracy charge.

A. Complaint Counsel Have Not Established A Specific Intent To Monopolize

Unable to establish that Upsher-Smith and Schering possessed the specific intent to monopolize, Complaint Counsel improperly rely on the Supreme Court decision in *United States v. Gypsum*, 438 U.S. 422 (1978), to argue that they need not prove anticompetitive intent for Your Honor to find "a horizontal restraint unlawful under the rule of reason." Opp. at 22.

Gypsum, however, is wholly inapposite as it was not a Section 2 conspiracy-to-monopolize case, but rather a Section 1 Sherman Act price-fixing case.[9]

Specific intent for a Section 2 conspiracy is far more demanding than the general-intent requirement of Section 1 claims. *See, e.g., In re Microsoft*, 127 F. Supp.2d at 730 n.4; *Wagner v. Magellan Health Servs., Inc.*, 121 F. Supp.2d 673, 681 (N.D. Ill. 2000) ("A conspiracy to monopolize under Section 2 is somewhat different than its Section 1 counterpart because of its heightened intent element, i.e., concerted action by knowing participants who have a specific intent to achieve a monopoly."). Complaint Counsel incorrectly argue that 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. *See* Opp. at 24. Yet as Judge Motz recently explained, specific intent actually "signifies ***something more*** than willing, voluntary, and knowing participation." *In re Microsoft*, 127 F. Supp. 2d at 731 (emphasis added). By contrast, as a general proposition of law, "knew or should have known" corresponds to a lesser, recklessness or negligence standard. *See, e.g., Farmer v. Brennan*, 511 U.S. 825, 836 (1994) (in civil cases generally recklessness means that the "risk of harm that is known or so obvious it should be known").

The cases cited by Complaint Counsel to support their "knew or should have known standard" actually reinforce the heightened specific-intent standard. *See* Opp. at 24 n.58 (citing cases). For example, contrary to Complaint Counsel's assertion, *Instructional Sys. Dev. Corp. v. Aetna Casualty & Surety Co.*, 817 F.2d 639 (10th Cir. 1987), does ***not*** state that a co-conspirator's intent can be inferred if it "knew or should have known" of monopolistic desires.

[9] For the same reason, Complaint Counsel's reliance on *United States v. Nippon Paper Indus. Co.*, 109 F.3d 1, 6 (1st Cir. 1997) is misplaced. That case also involved a Section 1 Sherman Act claim, not a Section 2 conspiracy to monopolize case.

Rather, that case found specific intent to monopolize because defendants Aetna and Doron made ***joint decisions*** to further Doron's goal of driving a competitor out of business, and explicitly expressed this desire in deposition testimony. *Id.* at 647; *see also Syufy Enter. v. Am. Multicinema, Inc.*, 793 F.2d 990 (9th Cir. 1984), cited at Opp. at 24 n.58 ("there was no showing that any of the distributors ***shared with Syufy a common purpose in monopolizing*** the hardtop theater market in the San Jose area") (emphasis added). In short, Complaint Counsel ignore the large body of well-established case law that proving a Section 2 conspiracy to monopolize claim requires the specific intent to further an illegal monopoly. *See* Mot. at 40 n.22 (citing more than 25 cases; all of which are Section 2 cases and all of which hold that evidence of specific intent is needed in order to establish a conspiracy to monopolize claim).

Examined under the proper legal standard, the facts offered by Complaint Counsel in their Opposition do not rise to the level of specific intent. For example, Complaint Counsel incorrectly argue that because both parties stood to benefit from Schering's monopoly, Upsher-Smith must have harbored the requisite specific intent. *See* Opp. at 24. Yet courts have rejected attempts to establish specific intent with mere evidence of mutual benefits. *See, e.g., Genetic Sys. Corp. v. Abbott Labs.*, 691 F. Supp. 407, 422 (D.D.C. 1988) (rejecting theory that "mutual purposes and intended effects" could satisfy specific intent standard); *Bldg. Ind. Fund,* 992 F. Supp. at 186 ("The essence of a conspiracy is not simply a commonality of interest").

None of the proferred evidence cited in Opposition establishes that Upsher-Smith had the specific intent to joint further an alleged Schering monopoly. The Agreement does not supply this evidence of specific intent. The misleading reference to the Schering Board presentation found at Opp. 5, to the effect that "Schering concluded that compensating Upsher-Smith for staying off the market was 'a prerequisite to any deal'" misquotes the Board presentation.

Nowhere does the Board presentation say that. See CX 338 at SP 12 00270; *see also id.* at SP 12 00268 ("we informed them that any such deal should stand on its own merit"). Further, the "Executive Summary" is facially benign as it lists licensing products from Upsher-Smith at a value to be determined as an option. See CX 283 at SP 018780 (Settlement Option IV: "Estimated value – Depends on products purchased"). In short, no evidence showed that Upsher-Smith actually formed the ***specific intent*** of ***jointly furthering any alleged Schering monopoly.*** No evidence exists of furtive conduct as Professor Bresnahan conceded, see Mot. at 42-43 (collecting references from Bresnahan cross examination); indeed, the Agreement was expressly conditioned on review and approval by the Schering Board. CX 348, Para. IX. at USL 3184. All of Upsher-Smith's sales activities after the Agreement in fact expressly deny any such shared intent. Mot. at 41-43.

B. Complaint Counsel's Reliance on Excluded Evidence Further Demonstrates Their Inability To Establish a Prima Facie Case of Conspiracy to Monopolize

In direct defiance of Your Honor's order, what little factual support Complaint Counsel offer in support of the conspiracy claim is based on excluded evidence. *See* Opp. 25 n.61 (citing CX 1494 (Driscoll IH); CX 1510 (Kapur IH) and CX 1508 (Hoffman IH)); *see also id.* at 4 n.7 (citing Kapur IH). At the pre-hearing conference, the Court ruled that investigational-hearing transcripts of Schering witnesses could not be used against Upsher-Smith:

> JUDGE CHAPPELL: I want to make it clear that I do not want anyone citing to a statement from a Schering-Plough witness in one of these hearings to be used against an Upsher-Smith witness or an Upsher-Smith — or the Upsher-Smith case…. ***That type of cite — that type of reference will not support a decision or an opinion of the Court.*** Is that clear?
>
> MR. MEIER: Yes, Your Honor.

Hrg. On Jan 23, 2002, Tr. 297-98 (emphasis added). Notwithstanding this express admonition, Complaint Counsel now cite those investigational hearing transcripts of Schering in their opposition brief against Upsher-Smith.

III. The Claims And Relief Sought In The Complaint Are Moot

Finally, the Complaint should be dismissed as it and the relief sought are moot. The primary relief sought by the Complaint was moot when Upsher-Smith began aggressively selling Klor Con M 20 on September 1, 2001.

Although Complaint Counsel abandoned the 180-day Hatch-Waxman Act exclusivity allegations in their response to Upsher's motion, Complaint Counsel nonetheless rely on *United States v. W.T. Grant Co.*, 345 U.S. 629 (1953) to argue that "The defendant is free to return to his old ways" when he voluntarily ceases the conduct. Opp. at 29 (citing *W.T. Grant*, 345 U.S. at 633). But here, as a matter of law, Upsher-Smith can never again "return to" the 180-day exclusivity on a generic K-Dur 20 product. As a matter of law Upsher-Smith is ***not capable*** of engaging in the alleged illegal conduct.

Upsher-Smith received notice from the FDA in January 1999 that it was the first filer under the Hatch-Waxman Act:

> Upsher-Smith Laboratories, Inc. was a first applicant to submit a substantially complete ANDA with a paragraph IV certification. Therefore, you are eligible for 180-days of market exclusivity for this drug product.

CX 611 at 2 (FDA Letter, dated Jan. 28, 1999). That exclusivity ended on February 28, 2002, as was established in Complaint Counsel's case in chief. CX 1481 (FDA Electronic Orange Book, Klor Con M20 exclusivity expires on February 28, 2002); Tr. 923:24-924:8 (Bresnahan concedes that 180 day period ends on February 28, 2002). Because the Hatch-Waxman Act only grants the 180-day exclusivity to a first filer, *see* 21 U.S.C. § 355(j)(5)(B)(iv) (2001) (Hatch-Waxman

Act), Upsher-Smith cannot have a second 180-day period. Indeed, no other firm will have a 180-day exclusivity period with respect to a generic version of K-Dur 20. "There is no reasonable expectation that the wrong will be repeated." *United States v. W.T. Grant Co.*, 345 U.S. at 633. As of February 28, 2002, any other firm can enter the market unhindered by the 180-day bar of the Hatch-Waxman Act. Therefore, Complaint Counsel's claims are moot. *See In re Am. Metal Prods. Co*, 60 F.T.C. 1667, 1962 FTC LEXIS 40, 51 (1962) (dismissing as moot a claim against a respondent that stopped purchasing "porcelain-on-steel sanitary ware").

Not surprisingly, Complaint Counsel all but conceded that they have failed to prove the "'cognizable danger of recurrent violation' needed to support an order prohibiting similar agreements in the future," by promising that "we will discuss [mootness] more fully in our post-trial brief . . . ." Opp. 30. Complaint Counsel, the party seeking an injunction, "must satisfy the court that relief is needed. The necessary determination is that there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive." *W.T. Grant Co.*, 345 U.S. at 633 (affirming court's refusal to award injunctive relief even though the action was not moot). *See also United States v. Oregon State Med. Soc'y*, 343 U.S. 326, 333 (1952). Complaint Counsel's suggestion that the mere presence of Upsher-Smith in the pharmaceutical industry suffices to overcome mootness, *see* Opp. at 30 ("neither Upsher-Smith nor Schering has exited the pharmaceutical industry") certainly does not warrant imposition of an injunction; membership in the pharmaceuticals industry is not a status offense. The relief sought in the Complaint has already been fully accomplished by the aggressive competition of Upsher-Smith Laboratories. The Hatch-Waxman 180-day exclusivity is awarded only to the first filer, and that period has expired.[10]

[10] The remainder of the relief sought would require conjecture and speculation on the part of the Court. There is simply no proof in Complaint Counsel's case in chief that Upsher-Smith is a party to any other patent settlement

CONCLUSION

For the foregoing reasons, as well as those set forth in the moving papers, Complaint Counsel's case should be dismissed.

Dated: March 25, 2002

Respectfully submitted,

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agreement. Compl. at Notice of Contemplated Relief, Para. 1. There is no proof that Upsher-Smith has ever agreed to refrain from conducting or assisting a study of the bioequivalence of any NDA holder's product. *Id*. at 2. There is no evidence that Upsher-Smith has entered into any agreement with an NDA holder that provides "anything of value" to Upsher-Smith in which Upsher-Smith "agrees to refrain from selling a drug product for any period of time." The absence of such proof after two years of discovery and investigation is striking.