**UNITED STATES OF AMERICA**
**FEDERAL TRADE COMMISSION**

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| **In the Matter of** | |
| **Schering-Plough Corporation, a corporation,** | |
| **Upsher-Smith Laboratories, Inc., a corporation,** | **Docket No. 9297** |
| | **Public Version** |
| **and** | |
| **American Home Products Corporation, a corporation.** | |

**RESPONDENT UPSHER-SMITH'S MOTION TO DISMISS DUE TO COMPLAINT COUNSEL'S FAILURE TO ESTABLISH A PRIMA FACIE CASE**

Under Rule 3.22(e) of the Commission's Rules of Practice, Upsher-Smith hereby moves for dismissal of Complaint Counsel's case in its entirety. The bases of this application are set forth in the accompanying memorandum of law.

Dated: February 15, 2002

Respectfully submitted,

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# UPSHER-SMITH'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS DUE TO COMPLAINT COUNSEL'S FAILURE TO ESTABLISH A PRIMA FACIE CASE

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## INTRODUCTION

In their case in chief, Complaint Counsel failed to make a prima facie showing as to several elements of the Complaint for which Complaint Counsel bear the burden of proof. Consequently, the Complaint should be dismissed for failure to prove a prima facie case.

As the basis for their novel contention that the Schering-Plough/Upsher-Smith settlement agreement was an unreasonable restraint upon competition, Complaint Counsel proffered Professor Bresnahan's three-part test. According to Professor Bresnahan, the issue of whether or not the June 1997 Settlement Agreement of the '743 patent infringement case was "anticompetitive" turns on the following questions:

> 1. Does the patent holder have monopoly power?
> 2. Is there a threat to that power? . . .
> 3. Is there a payment to the potential entrant to delay its entry? The payment can take any form as long as it is a net positive value to the entrant.

Tr. 655:15-656:6. According to Professor Bresnahan, these three elements are to be assessed as of the date the Agreement was entered into, June 17, 1997. *See* Tr. 659:17-661:13. But the factual evidence adduced by Complaint Counsel in their case in chief did not make a prima facie showing that Professor Bresnahan's three-part test was met at that critical date. This failure of proof, and others detailed below, requires the dismissal of the Complaint at this time — obviating the remaining weeks of trial.

## ARGUMENT

A motion to dismiss at the close of Complaint Counsel's case in chief must be granted if the record fails to establish a prima facie case in support of the Complaint. *See In the Matter of Uarco, Inc.*, 64 F.T.C. 924 (1964) (Commission upholding ALJ's grant of motion to dismiss for failure to establish prima facie case); *see also In the Matter of Consolidated Food Corp.*, 56 F.T.C. 1663 (1960). Although the evidence must be viewed in the light most favorable to the

complaint, only reasonable inferences may be drawn. *See In the Matter of Uarco, Inc.*, 64 F.T.C. 924 (1964) (Commission holding that it "cannot reasonably be inferred from the evidence of record" that the instances of off-list pricing had the requisite "adverse competitive effect"). Under this standard, neither Count I nor Count IV, the only counts against Upsher-Smith, can survive.

**1. Complaint Counsel Have Failed To Establish A Prima Facie Case That The Schering-Plough/Upsher-Smith Settlement Was Anticompetitive**

Count One alleges that the June 1997 Agreement is anticompetitive in that it "unreasonably restrains competition." Compl. ¶ 68. Complaint Counsel's case in chief was premised on the three-part test Professor Bresnahan created. Professor Bresnahan applied a test comprised of three critical elements to determine whether a settlement and license agreement in a patent infringement suit could be deemed "anticompetitive" in his view: "1. Does the patent holder have ***monopoly power***? 2. Is there a threat to that power? . . . 3. Is there a ***payment to the potential entrant to delay its entry***? The payment can take any form as long as it is a ***net positive value*** to the entrant." *See* Tr. 655:15-656:6 (emphasis added). The critical time frame for evaluating the reasonableness of the June 1997 agreement is at the time that the agreement was entered into. *See* Tr. 659:17–661:13 (each element of Bresnahan test must be evaluated as of the time June 1997 Agreement was entered into).

Bresnahan was clear about when the "monopoly power" must be established — Schering must have had "monopoly power" at the time of the June 1997 Agreement:

> Q. If neither Upsher-Smith nor Schering-Plough was a ***monopolist***, prong one would not be satisfied if we measured that as of June 1997. Isn't that correct?
>
> A. That's correct.

Tr. 661:10-13 (emphasis added); *see* Tr. 659:17-20 (all prongs measured as of June 17, 1997); *see also* Tr. 659:21-25, 660:1-15 . But these key factual elements of the Bresnahan Test were not proven in the case in chief at that critical time.

### A. Complaint Counsel Have Failed To Prove That Schering Was a Monopolist In The Relevant Product Market

Complaint Counsel have not established a prima facie case under Count 1 and, thus, it should be dismissed. Complaint Counsel bear the burden of defining the relevant product market in order to establish a prima facie case, and failure to do so is grounds for dismissal of the case. *See, e.g., Int'l Logistics Group, Ltd., v. Chrysler Co.*, 884 F.2d 904, 907-8 (6th Cir. 1989) (affirming summary judgment and directed verdict because "[t]he trial court correctly concluded that appellants failed to sustain their burden of defining and proving the relevant product market" and "[m]onopolization of a single brand is not an antitrust violation"); *Seidenstein v. Nat'l Med. Enters., Inc.*, 769 F.2d 1100, 1106, n.2 (5th Cir. 1985) (affirming motion for directed verdict because "[t]he fact that more individuals may prefer Sierra to other hospitals offering similar services" is no evidence "that Sierra is recognized as a separate and distinct market").[1]

Complaint Counsel have tried this case with their expert economist Professor Bresnahan asserting the existence of a relevant product market limited to a single product, K-Dur 20.[2] As

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[1] Under the rule of reason analysis, Complaint Counsel bear the burden of proving a prima facie case that the challenged settlement agreement is an unreasonable restraint of trade in a relevant market. *See Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163, 179 (1931); *Eichorn v. AT&T*, 248 F.3d 131, 138, 148 n.4 (3d Cir. 2001); *Virgin Atl. Airways Ltd. v. British Airways PLC*, 257 F.3d 256, 264 (2d Cir. 2001). Absent such showing of anticompetitive effect in a relevant market, a defendant need not proffer justifications for its conduct. *See, e.g., U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 596 (1st Cir. 1993); *Schachar v. Am. Acad. of Ophthalmology, Inc.*, 870 F.2d 397, 400 (7th Cir. 1989); *Rothery Storage & Van Co. v. Atlas Van Lines*, 792 F.2d 210, 229 (D.C. Cir. 1986); *Cowley v. Braden Indus.*, 613 F.2d 751, 754-55 (9th Cir.), *cert. denied*, 446 U.S. 965 (1980).

[2] As a technical matter, Bresnahan asserts that there exists a relevant product market for "20 mEq potassium chloride tablets and capsules," but with only one competitor until September 1, 2001. *See* Tr. 495:19-25, 679:19-25, 680:1-23. This is a curious choice, as there did not exist any 20 mEq capsules at the relevant time, Tr. 679:22-24, but there existed 20 mEq powders, which are mysteriously excluded. *See* Tr. 142:25, 143:1-2, 13-14, 144:15-21, 164:21-23 (Dean Goldberg). In any event, this gerrymandered product market by definition results in a one-product product market, a purported K-Dur 20-only product market until September 1, 2001.

demonstrated below, such single-product product markets are very rarely proved, and in this case, Complaint Counsel have failed to introduce competent evidence that establishes its alleged K-Dur 20-only relevant product market. The evidence adduced during the case in chief also failed to establish that physicians and patients "for clinical reasons" prefer 20 mEq extended release potassium chloride tablets over other forms of potassium chloride products. Compl. ¶ 24.

In an effort to support their artificially narrow product market, Complaint Counsel called two fact witnesses and one economist to provide testimony on this issue. Neither of Complaint Counsel's two fact witnesses provided factual testimony to support Complaint Counsel's defined product market or that physicians prefer "for clinical reasons" K-Dur 20 to other potassium chloride products. Both fact witnesses, Mr. Goldberg and Mr. Teagarden, testified to the contrary that the other potassium products were therapeutically equivalent to K-Dur 20. *See* Tr. 144:19-21 (Goldberg) and Tr. 259:10-17 (Teagarden).

### 1. Complaint Counsel's Customer Fact Witnesses And Expert Witness Did Not Provide Testimony To Support A K-Dur 20-Only Product Market

Both of Complaint Counsel's live customer witnesses — from Merck-Medco and United HealthCare — provided testimony that directly contradicted Complaint Counsel's alleged K-Dur 20-only product market. The high degree of interchangeability[3] between various potassium

[3] Courts consistently look to reasonable interchangeability as the primary indicator of a product market. *See Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) ("the outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it"); *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 400 (1956) (concluding that "cellophane's interchangeability with the other materials mentioned suffices to make it a part of this flexible packaging material market"); *see also United States v. Continental Can Co.*, 378 U.S. 441, 453-57 (1964) (glass jars and metal cans sufficiently interchangeable to be in the same market); *Tunis Bros. Co., Inc. v. Ford Motor Co.*, 952 F.2d 715, 722 (3d Cir. 1991) (concluding that the relevant product market consisted of "Ford and other comparable tractors" based on reasonable interchangeability); *Kaiser Aluminum & Chem. Corp. v. F.T.C.*, 652 F.2d 1324, 1330 (7th Cir. 1981) ("the clearest indication that products should be included in the same market is if they are actually used by consumers in a readily interchangeable manner"); *F.T.C. v. R.R. Donnelley & Sons Co.*, 1990-2 Trade Cas. (CHH) ¶ 69,239 at 64,854-55 (D.D.C. 1990) (offset and gravure print processes interchangeable and in the same product market); *Liggett & Myers, Inc.*, 87 F.T.C. 1074, 1163 (1976) (all dog food found to be in the same market in view of interchangeability of use), *aff'd*, 567 F.2d 1273 (4th Cir. 1977).

products, including 20 mEq sustained-release products, was confirmed by Dean Goldberg of United HealthCare. Goldberg stated that there is a substantial "degree of choice" in the potassium chloride market. *See* Tr. 126:25-127:22. Goldberg further testified that most, if not all, potassium chloride products are therapeutically equivalent. *See* Tr. 144:15-21 (discussing USX 277, United HealthCare's Preferred Drug List). Goldberg also confirmed that two 10 mEq potassium chloride products would have the same therapeutic effect as one potassium chloride 20 mEq product. *See* Tr. 145:3-17. Goldberg stated that taking two 10 mEqs instead of one 20 mEq would deliver the same amount of potassium and would have similar release times. *See* Tr. 174:8-175:10. Goldberg confirmed that reasonable substitutes exist to the 20 mEq sustained release potassium chloride product and, more importantly, that physicians consistently prescribe those products. *See* Tr. 145:3-17.

The actions of "demanders" of potassium chloride products also fail to support Complaint Counsel's narrow product market. Large physician benefit managers ("PBMs"), such as Merck-Medco, the country's largest PBM, do not recognize 20 mEq sustained-release potassium chloride products as a distinct market separate from the overall potassium chloride products market. Russell Teagarden, who is responsible for maintaining and updating Merck-Medco's prescription formulary, testified that there is no separate listing for 20 mEq potassium chloride products on its formulary. *See* Tr. 234:7-10 (discussing USX 125); 240:21-24 (discussing USX 127). Clearly, if Merck-Medco and other PBMs thought that unique characteristics existed that warrant a separate market for just 20 mEq sustained-release potassium chloride products, there would be a separate classification on Merck-Medco's formulary.

Both fact witnesses testified that a number of potassium products can treat potassium deficiencies beyond just 20 mEq sustained-release potassium chloride tablets and capsules. *See*

Tr. 126:20-127:22 (Goldberg); 259:10-17 (Teagarden). Both customer witnesses further confirmed that other potassium products and dosages are interchangeable with the 20 mEq extended-release chloride product. *See* Tr. 174:24-175:10; 257:25-258:4. Moreover, each of Complaint Counsel's witnesses conceded that physicians can prescribe two 10 mEq potassium chloride products for one 20 mEq potassium product. *See* Tr. 145:3-17; 257:25-258:6. This testimony cuts directly against Complaint Counsel's attempt to establish a separate and distinct product market.[4] In the end, Merck-Medco's and United HealthCare's witnesses only provide convincing factual support that Complaint Counsel's alleged product market is unrealistic and far too narrow.

The testimony and analysis of Complaint Counsel's economist also fail to establish any evidence of the viability of a narrow relevant market. Professor Bresnahan's testimony and analysis fail to support his conclusion that the relevant product market for analyzing this agreement is "20 mEq sustained release potassium chloride tablets and caplets." *See* Tr. 1282:20-24. Bresnahan did no systematic statistical or econometrics work, *see* Tr. 690:10-16; 810:20-811:4; failed to consider key portions of relevant Schering and Upsher-Smith documents and testimony, *see* Tr. 684:21-685:17; 723:18-724:10; 845:15-22 850:8-851:12; failed to conduct even a cursory survey of demanders of potassium chloride products (doctors, pharmacists, HMOs, and others), *see* Tr. 690:17-692:18; failed to obtain a set of pricing data with which to compare Schering's prices against other potassium products' pricing, *see* Tr. 725:6-11; 867:10-13; failed to measure the cross-elasticity of demand between competing potassium products, *see* Tr. 810:20-24; failed to evaluate the impact of detailing and advertising, *see* Tr. 651:25-652:4;

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[4] Bresnahan himself has not studied the issue of "therapeutic equivalence" between taking two 10 mEq potassium tablets such as Klor Con 10 versus taking a K-Dur 20; as far as he knows, they are therapeutically equivalent. *See* Tr. 704:5-13.

877:10-22; and failed to conduct any type of econometric analysis in arriving at his conclusion regarding the relevant antitrust market. *See* Tr. 689:24-690:1.

Professor Bresnahan's own testimony confirmed that his conclusion that the relevant antitrust market consisting of K-Dur alone is too narrow of a product market. Bresnahan conceded that his analysis ignored the rest of the products in the potassium chloride market. *See* Tr. 867:6-868:1. [

] Bresnahan testified that in preparing his expert report, he repeatedly chose to ignore documents that showed that numerous other competitors compete vigorously in the potassium chloride products market. *See* Tr. 721:11-14 (Bresnahan did not reference in his report the phrase "crowded market" used by Schering to describe the potassium market in its Schering K-Dur marketing documents); 684:21-685:17; 724:8-10; 845:15-21; 850:8-851:15. His analysis contained no examination of the other products in the potassium chloride market. *See* Tr. 725:6-11; 689:17-690:1; 651:25-652:4.

The remainder of Professor Bresnahan's analysis regarding the relevant product market consisted of repeated quoting from selected depositions and Schering and Upsher-Smith business documents. His analysis was so narrow that the statements he quoted from documents and deposition testimony appear to completely ignore contradictory statements in subsequent paragraphs and pages. Bresnahan repeatedly failed to consider key portions of Schering's documents that clearly showed Schering considered K-Dur to be a part of a larger potassium chloride market. *See* Tr. 709:23-710:12; 710:24-711:15; 712:13-713:4; 721:11-14; 814:2-6; 816:7-817:17; 824:21-825:1; 825:10-17 (Schering marketing plans referring to market made up

of other KCL supplements as well). He further ignored numerous documents that showed Upsher-Smith directly targeting K-Dur 20 with its sales plan to push two 10 mEqs for the one 20 mEq product. *See* Tr. 864:10-13 (discussing Uspher-Smith ad intended to highlight advantages of Klor Con 10 versus K-Dur 20). There is also no acknowledgement in Bresnahan's analysis that Schering recognized that throughout the relevant period, generic potassium chloride manufacturers were gaining market share at K-Dur's expense. *See* Tr. 709:4-9; 716:12-18; 731:13-733:3; 813:4-7; 825:14-17; 829:7-12 (referring to Schering K-Dur marketing documents — CX 13, 18, 20 — that demonstrate Schering's concern over market share lost to generics). Professor Bresnahan wholly ignored, without explanation, key sections of Schering's and Upsher-Smith's business documents that are critical to any analysis of the relevant product market. *See* Tr. 684:21-685:17; 724:8-10; 845:15-21; 850:8-851:12 (occasions where Bresnahan failed to note contradictory statements, from portions as close as one line from the source of his direct quotes).

Professor Bresnahan's conclusion as to the product market also fails because he did no econometric or sampling analysis to determine the cross-elasticity of demand. Professor Bresnahan admits that he did not perform any regressions or any form of econometric analysis to determine the cross-elasticity of demand for potassium chloride products, including K-Dur 20. *See* Tr. 690:10-16; 810:20-811:4 (Bresnahan has not performed regression analysis on potassium products, nor other quantitative analysis of cross-elasticity of demand between K-Dur 10 and K-Dur 20). Bresnahan also admitted that he did not survey any demanders of potassium chloride supplements, such as PBMs, hospitals, physicians, consumers or chain drug stores. *See* Tr. 690:17-692:18. Without even a cursory analysis of the cross-elasticity of demand or a sampling analysis, Bresnahan's analysis is incomplete and flawed.

**The *Brown Shoe* Factors Support A Broader Potassium Product Market.** Complaint Counsel have failed to establish their alleged relevant market under the test identified in the Supreme Court's decision in *Brown Shoe*, 370 U.S. 294 (1962). Courts have traditionally looked at the seven *Brown Shoe* factors to determine if products should be in separate relevant markets in an antitrust analysis. *See Brown Shoe*, 370 U.S. at 325-26.[5] Complaint Counsel's witnesses have failed to competently establish any of these factors in order to establish their artificially narrow product market. Instead, undisputed record evidence weighs convincingly under these factors against the proposed definition of a product market.

First, Complaint Counsel have clearly failed to show that the industry recognizes the existence of distinct markets between potassium chloride products and 20 mEq sustained-release potassium chloride tablets and capsules. Complaint Counsel's own fact witnesses from Merck-Medco and United HealthCare provided no testimony to show that the industry recognizes 20 mEq sustained-release potassium chloride products as a separate and distinct market from the overall potassium chloride market. Complaint Counsel also failed to call any witnesses such as a pharmacist, physician, consumer or pharmacologist to provide testimony to support their narrow market. In fact, of the fact witnesses Complaint Counsel did call on this issue, Mr. Teagarden testified that Merck-Medco's prescription formulary ***does not*** have a separate listing for 20 mEq potassium chloride products. *See* Tr. 234:7-10. Professor Bresnahan acknowledged that the record shows that health care organizations, doctors, and advertising by manufacturers all encourage the interchangeability and equivalence of other potassium chloride products to K-Dur 20. Even more importantly, Bresnahan conceded he could not cite any pharmaceutical trade

[5] The seven *Brown Shoe* "practical indicia" factors are: (1) the industry recognizes distinct product markets; (2) the products are manufactured in different facilities; (3) each group of products has characteristics peculiar to itself rendering it generally noncompetitive with the others; (4) each group of products is directed toward a distinct class of customers; (5) each has distinct prices; (6) there is little price sensitivity between the markets; and (7) specialized vendors. 370 U.S. at 325.

periodicals that treat K-Dur 20 as a product that has unique features. *See* Tr. 711:8-12; 1271:25-1272:5.

Professor Bresnahan also conceded that Schering's documents use the entire potassium chloride supplement market as a measure of performance and also consider other products such as 10 mEq potassium chloride products as competitors to K-Dur 20. *See* Tr.709:23-710:10; 721:11-14; 814:2-6; 816:6-817:17; 824:21-825:1; 825:10-17 (Schering marketing plans referring to market made up of other KCL supplements as well) (CX 18, 20). Bresnahan could not refute that Schering considers the overall potassium market to be a "crowded market." *See* Tr. 720:23-721:10. Bresnahan further testified that IMS, the industry data source, lists a number of products under its category "potassium products." *See* Tr. at 889:11-18 (including powders, tablets, capsules, etc.). Even Bresnahan and Complaint Counsel relied on Schering business documents that combined K-Dur 10 and K-Dur 20 in the same charts and business plans. *See, e.g.*, Tr. 816:15-18. [

] It cannot be gainsaid that the industry recognizes a broad potassium market, and Complaint Counsel adduced no industry publications or recognition of a K-Dur 20-only product market.

Second, Complaint Counsel have presented no evidence that K-Dur 20 and its generic equivalents are manufactured in different plants or require different production facilities. In fact, Professor Bresnahan admitted that the 10 and 20 mEq products are in fact produced in the same plant. *See* Tr. 1272:6-8 (K-Dur 10 and K-Dur 20 are manufactured in the same Schering factory).

Third, Complaint Counsel have failed to show that K-Dur 20 has unique or peculiar characteristics that render it insulated from competition from other potassium chloride products. In fact, Complaint Counsel's only two customer witnesses on this issue and their economic expert conceded that a number of potassium products, including K-Dur 20, compete in the potassium chloride market. *See* Tr. 126:20-127:22 (Goldberg); 259:10-260:15 (Teagarden); 744:1-18; 704:11-13; 1270:22-1271:2 (Bresnahan). All three witnesses confirmed that potassium products are produced for the ***same purpose*** of treating hypokalemia and are clinically interchangeable. *Id.* (witnesses confirmed that a number of potassium products are used to treat potassium deficiency). Further, Bresnahan conceded that K-Dur 20 faces compliance problems, like other potassium chloride products in the market, and thus there is no unique dosing advantage to a 20 mEq sustained-release potassium chloride tablet and capsule. *See* Tr. 725:12-729:5; 742:18-21; 828:17-829:6. Consistent with the pharmaceutical industry's lack of recognition of a distinct K-Dur 20-only market, doctors do not perceive K-Dur 20 as being a unique potassium product. *See* Tr. 722:10-724:2.

Fourth, Complaint Counsel adduced no evidence that K-Dur 20 is directed toward a distinct class of customers. Instead, Bresnahan testified that there is no distinctive class of customers that prefer K-Dur 20.

> Q. And sir, sitting here today, you have no basis, based on a patient's demographic background, that is, age, sex, race, to identify any subclass of patients for whom K-Dur 20 was the only appropriate potassium treatment, do you, sir?
>
> A. No, not based on demographics or other classification criteria.

Tr. 1271:18-24. *See also id.* Tr. 707:17 – 707:21 (Bresnahan unaware of any group of potassium deficient patients that cannot by treated by Klor Con 10; Bresnahan "has seen nothing in those terms."). Bresnahan conceded that K-Dur 20, Klor Con 8 and 10, Micro-K, K-Tab, Slow K, K-

Lyte, Klotrix, Apothecon KCL and Ethex potassium chloride were all prescribed for the same "purpose" of treating potassium deficiency. *See* Tr. 1270:22 – 1271:17.

As for patient compliance, Bresnahan testified that patient compliance issues were also significant concerns to the Schering marketing executives for K-Dur 20. CX 20 at SP 4040-41 (compliance a "challenge"; "only 22% of patient retention after 12 months"); *see* Tr. 753:9-20. And Bresnahan conceded that for some patients, the large size of the K-Dur 20 tablet made it "hard to swallow." CX 746 (K-Dur Backgrounder) at SP 23 00378; *see id.* SP 23 00378 (dissatisfaction with K-Dur 20 was "high" due to "rough finish of the tablet which makes it difficult to swallow, have experienced stomach irritation and its cost"); *id.* at SP 23 00379 ("Size of [K-Dur 20] pill makes it difficult to swallow"). Bresnahan had not even considered the physical characteristics of the K-Dur 20 tablet vs. the Klor Con 10 tablet until Respondent Upsher-Smith's opening statement. *See* Tr. 725:12-726:25. The record evidence does not show that doctors consider the 20 mEq dosage to be important. In fact, "few" of the doctors who received Schering's detailing materials on K-Dur 20 reported that K-Dur 20 had a 20 mEq dosing. CX 746 (K-Dur Backgrounder) at SP 23 0076.

Fifth, the pricing evidence does not support Complaint Counsel's case. Under this factor, for products lines to be considered separate, each potentially definable market must have distinct prices. Complaint Counsel have failed to introduce any evidence or testimony of distinct prices in the 20 mEq sustained-release potassium chloride tablet and capsule market, as compared with other potassium products. Instead, Complaint Counsel's own witness, Mr. Teagarden, conceded that K-Dur has the same relative price as other potassium chloride supplements. *See* Tr. 224:17-19; 215:22-24; 218:2-6. Bresnahan conceded that branded potassium products had "comparable" prices to K-Dur 20. *See* Tr. 730:8-13. The only specific pricing difference that appeared in

Bresnahan's Report was a 30% pricing difference between only a small group of the potassium unbranded generic products, and this difference actually proved the cross-elasticity of demand between unbranded generics and K-Dur 20 in 1996, as discussed below. Bresnahan presented Your Honor with no statistical pricing study, *see* Tr. 1274:6-10; and did not even have a pricing data set for K-Dur 20, *see* Tr. 834:13-16; a price data set for K-Dur 10, *see* Tr. 834:17-19; for Klor Con 10, *see* Tr. 834:20-22; and for its competitors in the sale of potassium supplements. *See* Tr. 867:10-13; *see also* Tr. 835:1-5 (no data set for 1995-2001 for "other potassium chloride products").

Bresnahan concedes that, as under the case law, a pricing difference alone does not suffice to prove a separate product market, as he testified. *See* Tr. 1002:2-8 (existence of a price differential between Bayer aspirin and generic aspirin is not sufficient evidence to conclude that Bayer aspirin is in a separate product market from other asprin). Nor did he study the demand for various forms of potassium to calculate demand elasticities. *See* Tr. 810:12-15; 810:20-811:7.

And post-September 1, 2001 pricing behavior does not support Bresnahan's K-Dur-20-only product market. As before, Bresnahan has not studied the trend of K-Dur 20 pricing since September 1, 2001. *See* Tr. 1003:6-8. Bresnahan has not reviewed any systematic statistical data on K-Dur 20 pricing since that date. *See* Tr. 1274:6-14. Bresnahan does not know, as of the date of his testimony January 31, 2002, whether the price of K-Dur 20 has dropped at all since September 1, 2001. *See* Tr. 1274:11-14.

The one example of post-September K-Dur 20 Pricing Bresnahan was shown indicated the fallacy hidden in his K-Dur-only theory; history proves too much. Post-September 1, 2001, Bresnahan was shown one example at an area pharmacy that, K-Dur 20 was selling at 30%

above Klor Con M20, suggesting that K-Dur 20 is, under Bresnahan's logic, today in a separate product market — a result that Bresnahan cannot "necessarily" rule out. *See* Tr. 1004:11-25.[6] Schering did not project a price decrease for K-Dur 20. *See* CX 133; TR. 767:12-769:20. Bresnahan went on to note that the prior literature suggests that AB rated generics do not lower branded pricing, *see* Tr. 1194:24-1195:14, a result at odds with competitive models. *Id.* Such absurd results can only be posited when one ignores the market realities and documented interplay of Klor Con 8 and 10, Micro-K, other branded generics, and generic potassium products with K-Dur 20, set forth throughout all of the Schering K-Dur marketing documents beginning in 1995.

**Single-product, single-brand product markets are exceedingly rare.** Bresnahan did not evaluate the brand advertising conducted by Schering. Schering-Plough put millions of dollars into promoting the K-Dur brand and K-Dur 20 during the 1995-1997 time period. *See* Tr. 733:13-20; 734:4-14 (Schering substantially outspent competitors in promotional advertising by as much as 100-fold in advertising and detailing); CX 18 at SP 23 00064 ($9.5 million K-Dur budget). This was an aggressive strategy to create brand awareness by doctors. *See* Tr. 714:14-18; CX 13. But creating brand awareness by doctors of K-Dur is not "anti-competitive or illegal." *See* Tr. 714:19-22.[7]

As a matter of law, brand names constitute natural monopolies that do not violate U.S. antitrust statutes, and courts are highly skeptical of single brand product markets. *See, e.g.,*

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[6] If K-Dur 20 and Klor Con M 20 are in separate product markets, of course, this case is meaningless.

Moreover, the effect of mandatory substitution laws has not been rigorously studied here. Complaint Counsel concede that mandatory substitution laws, which prevent K-Dur 20 from competing with other products and force substitution, require a shift to AB-rated generics and account for a reduction in the sales of K-Dur 20. *See* Complaint Counsel Trial Brief at 12 ("Some states ***require*** such substitution where the product is paid for by the state Medicaid plan or other public assistance") (emphasis added).

[7] There is no evidence of misleading advertising in this case. *See* Tr. at 651:22-24 (Bresnahan).

*United States v. E.I. du Pont de Nemours and Co.*, 351 U.S. 377, 393 (1956) ("one can theorize that we have monopolistic competition in every nonstandardized commodity with each manufacturer having power over the price and production of his own product. However, this power that, let us say, automobile or soft-drink manufacturers have over their trademarked products is not the power that makes an illegal monopoly."); *Brokerage Concepts, Inc. v. U.S. Healthcare, Inc.*, 140 F.3d 494, 513 (3d Cir. 1998) (rejecting plaintiff's proposed "single brand market consisting solely of U.S. Healthcare members with prescription drug benefits"); *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997) (rejecting plaintiff's proposed relevant market of "those products currently approved by Domino's Pizza, Inc. for use by Domino's franchisees"); *Town Sound and Custom Tops, Inc., v. Chrysler Motors*, 959 F.2d 468, 480 (3rd Cir. 1990) (refusing to find that the Chrysler brand formed its own product market); *Re-Alco Indus. Inc. v. Nat'l Ctr. For Health Educ., Inc.*, 812 F. Supp. 387, 391 (S.D.N.Y. 1993) (motion to dismiss granted where plaintiff alleged single product market consisting of the market for a single health care education manual).[8]

Under the sixth *Brown Shoe* factor, in order to have separate markets, Complaint Counsel must establish that minimal price sensitivity exists between products. Complaint Counsel has not introduced any evidence that there is minimal price sensitivity between other potassium chloride supplements and K-Dur 20. In fact, Complaint Counsel cannot introduce such evidence because their expert failed to conduct the analysis necessary to determine the degree of price sensitivity between 20 mEq sustained-release products and other potassium products. *See* Tr. 689:17-690:1; 690:10-16; 810:20-24 (Bresnahan has not done any econometric or regression

[8] *See also Deep South Pepsi-Cola Bottling Co. v. PepsiCo, Inc.*, 1989-1 Trade Cas. (CCH) ¶ 68550 (S.D.N.Y. 1989); *Theatre Party Assocs. Inc. v. Shubert Org., Inc.*, 695 F. Supp. 150, 154 (S.D.N.Y. 1988) (requiring "a theoretically rational explanation" to support plaintiff's proposed relevant product market of tickets for one particular Broadway show).

analysis to analyze price sensitivities between potassium chloride supplements.). The record evidence actually shows not only price sensitivity in the market, but also K-Dur 20 losing some market share to other potassium chloride products. *See* Tr. 710:24-711:23; 712:13-713:18 (CX 13: showing K-Dur 20 is under pressure from generics); 743:20-25; 744:24-745:6 (CX 18: market data shows that higher K-Dur price was causing some demanders to switch to generics); 751: 2-4 (CX 18: "Generic competition [including Klor Con 10] continues to grow at the expense of K-Dur 20").

The seventh *Brown Shoe* factor asks as to whether there are "specialized vendors" unique to K-Dur 20. No specialized vendors serve only K-Dur 20. Again, Professor Bresnahan acknowledged that both Klor Con and K-Dur 20 are dispensed by pharmacies in response to prescriptions written by doctors. Both drugs are prescription medications for potassium. *See* Tr. 696:7-10; *see* Tr. 696:24-697:13 (both products are prescribed; no switching costs between the two products). Patients who are hypokalemic receive prescriptions for a potassium supplement when they visit the doctor. *See* Tr. 696:16-19. Demand for both products begins when a patient presents himself to a doctor. *See* Tr. 696:11-15. Prescriptions are dispensed for both products at pharmacies. *See* Tr. 697:14-699:9.

Instead, the record evidence, which was only brought out on cross, was that the 30% price difference between K-Dur 20 and the unbranded generic potassium products was ***causing*** the sales of the generic products to rise, as set forth in the K-DUR Marketing Plan (CX 20), written just six weeks after the June 1997 Agreement became effective:

> **Generic competition continues to grow at the expense of K-DUR 20.** Klor Con 10, a branded generic, has grown to 16% of total prescriptions. The category of generics has grown over a full point to 30% of total prescriptions. ***The growth in the generic market is due in part to the 30% price advantage over K-DUR 20,*** but managed care also plays a significant role.

CX 20 (1998 K-DUR Marketing Plan, August 1, 1997, at SP 4040) (emphasis added); *see* Tr. 829:7-22 (Bresnahan understands from CX 20 that Schering was losing "some sales" of K-Dur 20 to generic potassium).

### 2. The Market Share Of Schering's K Dur-20 Product In June 1997 Was Below Forty Percent Of The Relevant Product Market, Precluding Any Finding Of "Monopoly Power" Under The Bresnahan Rule

The fundamental premise of the case is that Schering-Plough was a monopolist in the sale of 20 mEq tablets by selling the only such product, K-Dur 20, at the time it entered into the June 1997 Agreement. *See* Compl. ¶ 70 ("Schering has monopoly power in the manufacture and sale of potassium chloride supplements approved by the FDA and narrower markets contained therein . . . ."); Complaint Counsel Trial Brief at 16 ("Bresnahan will explain . . . that Schering had monopoly power in K-Dur 20."); *see also* Bresnahan Test, cited infra at p.3, Tr. 660:6-15 (Bresnahan testifying that Bresnahan test is to be applied at the time the agreement is entered into, June 1997). At trial, Bresnahan explicitly premised his three-part test or rule on the existence of Schering's "monopoly power" as of June 1997. *See* Tr. 659:11-20 (Bresnahan Test), quoted supra.

Complaint Counsel have failed to establish that Schering had "monopoly power". To establish "monopoly power" Complaint Counsel must establish a relevant product market. *See Walker Process Equip. Inc., v. Food Mach. and Chem. Corp.*, 382 U.S. 172, 177 (1965) (establishing product market is necessary to evaluate monopoly power; "[w]ithout a definition of that market there is no way to measure [the defendant's] ability to lessen or destroy competition."); *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 392-93 (1956)

("Illegal [monopoly] power must be appraised in terms of the competitive market for the product.").[9]

Fundamentally, Professor Bresnahan's testimony confirmed that Schering does not have "monopoly power" in the relevant market because Schering's business documents, the source of Professor Bresnahan's analysis, demonstrate that Schering believed that its "market share" did not exceed 40% in the relevant period of total prescriptions for potassium. *See, e.g., Blue Cross & Blue Shield v. Marshfield Clinic*, 65 F.3d 1406, 1411 (7th Cir. 1995) ("50% is below any accepted benchmark for inferring monopoly power from market share") (citations omitted; collecting cases).[10]

Bresnahan testified that despite an extensive review of Schering's business records, no Schering document demonstrated that Schering executives believed they had a monopoly and no document said that Schering had a 100% share of the potassium market. *See* Tr. 746:9-13. Professor Bresnahan further conceded that he had located no document in which Schering executives believed that they had greater than 70% "market share" with the sale of K-Dur 20, as

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[9] *See also Spectrum Sports, Inc., v. McQuillan*, 506 U.S. 447, 455 (1993) (to establish monopolization or attempted monopolization it is "necessary to appraise the exclusionary power of the illegal patent claim in terms of the relevant market for the product involved.") (citing *Walker Process*); *Alcatel USA, Inc., v. DGI Tech., Inc.*, 166 F.3d 772, 784 (5th Cir. 1999) (affirming grant of defendant's motion for a judgment as a matter of law because claimant, in "trying to define the market as narrowly as possible (in order to make it look as if [defendant] had market power)," did not "present legally sufficient evidence of customers facing significant information and switching costs" and their proffered relevant market did not "comport with market realities") (citations omitted); *Queen City Pizza, Inc., v. Domino's Pizza, Inc.*, 124 F.3d 430, 436-37 (3rd Cir. 1997) (affirming dismissal for "failure to plead a valid relevant market;" "Where a plaintiff fails to define its proposed relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand, or alleges a proposed relevant market that clearly does not encompass all interchangeable substitute products even when all factual inferences are granted in plaintiff's favor, the relevant market is legally insufficient and a motion to dismiss may be granted.") (citations omitted); *Smalley & Co. v. Emerson & Cumming, Inc.*, 13 F.3d 366, 368 (10th Cir. 1993) (holding a plaintiff distributor's narrow definition of a relevant market was fatal to its antitrust case because "a plaintiff must prove a defendant had 'the power to control prices or exclude competition' in the relevant product market. A plaintiff's case must include proof of the relevant market.") (citations omitted).

[10] *See Acme Markets, Inc. v. Wharton Hardware and Supply Corp.*, 890 F. Supp. 1230, 1241-42 (D.N.J. 1995) (40% of market share insufficient); *Abrams v. Anheuser-Busch, Inc*, 811 F. Supp. 848, 873 (E.D.N.Y. 1993) ("39% share is below that which has been deemed sufficient to confer market power").

they viewed the "market share." *See* Tr. 875:24-876:7 (Bresnahan not aware of "any Schering business document that states that K-Dur 20 had a 100 percent market share of a 20 mEq only product market"); Tr. 876:8-12 (Bresnahan not aware of any Schering document from 1995 to 2001 that "expresses a market share for K-Dur 20 in excess of 70 percent"); Tr. 876:13-16 (Bresnahan not aware of any Schering document expressing a "market share" for K-Dur 20 in excess of 60%).

Complaint Counsel's proof only succeeded in demonstrating that there is no evidence that Schering had monopoly power in the potassium chloride market. Complaint Counsel have called only two "customer" witnesses: Mr. Goldberg from United HealthCare and Mr. Teagarden from Merck-Medco. Both fact witnesses testified that there are a number of competing potassium products that are manufactured and prescribed for potassium deficiency. *See* Tr. 126:20-127:22; 154:7-14 (Goldberg from United HealthCare stated that there are between 12 to 16 potassium chloride products on its Preferred Drug List and 24 combinations of potassium products available); 259:10-17 (Merck-Medco's Teagarden conceded a number of potassium products treat potassium deficiencies). Additionally, both Merck-Medco's and United HealthCare's witnesses confirmed that a physician can prescribe two 10 mEq tablets or capsules for one 20 mEq tablet or capsule for a therapeutically equivalent dose of potassium. *See* Tr. 174:24-175:10 (Goldberg said two 10s deliver the same potassium and release at about the same time as one 20 mEq); 257:25-258:6 (Merck-Medco's witness said a doctor can prescribe two 10 mEq potassium chloride tablets instead of a single dose 20 mEq tablet.).

The uncontested testimony of the fact witnesses was corroborated by Complaint Counsel's expert economist. Bresnahan conceded that Upsher-Smith's other potassium chloride products compete with Schering's K-Dur 20. *See* Tr. 744:1-7. The sheer volume of competitors

in the potassium chloride products market is directly inconsistent with any indication of monopoly power.

Complaint Counsel's witnesses actually confirmed that Schering's market share is ***not*** indicative of monopoly power. Professor Bresnahan repeatedly conceded that he had not considered Schering's business documents demonstrating that Schering had approximately 30-38% market share of potassium prescriptions, while generic manufacturers had between 60-70% of the potassium chloride market. *See* Tr. 1277:1-21 (CX 18: actual market share of K-Dur 20 is less than 37 percent); 819:1-4 (CX 20: 1997 chart showing combined market share for both K-Dur 10 and 20 is 38 percent); 710:7-12 (CX 13: Schering believes it has 29 percent "market share" of TRX — total prescriptions — for potassium); 748:25-749:8 (CX 18: K-Dur 10 and 20 had in 1996 a combined "market share" of 37 percent of potassium, measured in TRX, total prescriptions). In these documents, Bresnahan conceded that Schering's documents indicated that it had no greater than 40% of the potassium chloride market.[11] And these documents are more favorable to Complaint Counsel because they combine the sales of K-Dur 20 with K-Dur 10, as Professor Bresnahan acknowledged. *See* Tr. 819:1-4. United HealthCare's Goldberg corroborated the Schering business documents' view of "market share" and indicated that Schering did not possess monopoly power. Goldberg testified that K-Dur 10 and 20 mEq dosages combined represent only 30% of United HealthCare's own potassium prescriptions as of August 2001. *See* Tr. 163:21-164:6.

Less than 45 days after the June 17, 1997 Agreement, Schering-Plough wrote a K-Dur Marketing Plan for 1998, dated August 1, 1997. CX 20; *see* Tr. 815:24-25. Just after execution

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[11] These business documents are important because they are the very same documents that Professor Bresnahan relied upon. Moreover, where, as here, the expert only read business documents, the business documents are the sum and substance of his analysis. There is no econometric, statistical or survey data introduced by Complaint Counsel in this case.

of the June Agreement, Schering was estimating its "market share" at only 38% of TRX for potassium, CX 20 at SP 4034 (page 5), Tr. 819:1-4, and this "market share" combined the sale of K-Dur 10 and K-Dur 20, Tr. 819:1-3, thus, 38% overstates the "market share" of potassium TRX that K-Dur 20 represented at that time. *See* Tr. 1279: 8-23 (K-Dur 20 had less than "38%" "market share" of potassium). As of August 1, 1997, Schering's K-Dur Marketing Plan demonstrates that "a majority of the potassium prescriptions" in the US were not accounted for by the sale of K-Dur. *See* Tr. 818:8-25 (Bresnahan: per CX 20, "62%" of TRX for potassium "were not accounted for by K-Dur products"); *see* Tr. 817:1-6 (Bresnahan: CX 20 "pie chart" shows "market share for K-Dur is now 38 percent"). *See* CX 20 states that Schering's "major competitors" for K-Dur are Klor-Con (Upsher-Smith's product brand) and generic potassium. *See* CX 20 at SP 4035; CX 20 at SP 4037. CX 20 also indicates that Schering at this time was expanding its output by increasing the TRX — total prescriptions — it was garnering for K-Dur. *See* CX 20 at SP 4035; Tr. 820:16-19 (Bresnahan: "they [Schering] were expanding the output over time," discussing CX 20); *see also* Tr. 819:14-25, 819:24-820:2 (same); Tr. 822:18-20 (same).

Complaint Counsel failed to demonstrate two factors that exist if Schering did possess monopoly power in the time before and after the June 1997 settlement agreement. There is no record evidence that Schering reduced output; instead, through aggressive marketing and detailing it was growing its TRX, as the K-Dur Marketing Plan, issued on August 1, 1997, demonstrates. *See* CX 20 at SP 4035 (K-DUR TRXs 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).

Bresnahan even conceded that Schering did not decrease output, but rather increased both output and its sales and marketing efforts. *See* Tr. at 820:16-19; 821:18-24; 822:18-20.[12]

As of August 1, 1997, Schering executives also believed that they continued to lose sales to Upsher-Smith's Klor Con line of potassium products (at this time the 10 mEq and 8 mEq) as well as to "generic potassium." *See* CX 20 (K-Dur Marketing Plan, Aug. 1, 1997) at SP 4035; CX 20 at SP 4040 ("Generic competition continues to grow at the expense of K-DUR 20. Klor Con 10, a branded generic, has grown to 16% of total prescriptions. The category of generics has grown over a full point to 30% of total prescriptions."). The growth in sales in Klor Con and generic potassium in the summer of 1997 meant that Schering's K-Dur product line was "losing some sales" to these competing sets of products. *See* Tr. 829:13-22. Schering also noted in CX 20, its Summer 1997 K-Dur Marketing report, that "Usage data for 10 mEq generics shows that most patients are using 2 tablets a day, a dose equivalent to one K-Dur 20." *See* CX 20 SP 4040; *see* Tr. 833:2-6. Bresnahan's Report failed to mention this fact. *See* Tr 833:7-9. Schering's data source for its K-DUR Marketing Plan, written in summer 1997, was IMS data. *See* Tr. 832:5-20; CX 20 (passim).

Complaint Counsel also failed to establish that any barriers to entry exist which permit Schering to enjoy monopoly power. Complaint Counsel failed to produce any witnesses or evidence demonstrating that the barriers to entry are prohibitive to quick and easy entry. Rather, the overwhelming evidence in the record is there are a number of branded and generic potassium chloride products manufactured by numerous companies and thus entry is easy. *See, e.g.,see* Tr. 226:15-228:6 (branded competitors in potassium chloride market). The sheer volume of potassium chloride manufacturers and products indicates that both de novo entry and entry

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[12] Schering's conduct is directly contrary to what is expected from a firm that is allegedly enjoying monopoly power in a relevant product market under the case law.

through acquisition of a firm's potassium product line provide two effective ways for potential entry into the potassium chloride market. And Bresnahan testified that a number of leading pharmaceutical firms were selling potassium products throughout the relevant time period.

In this case, uncontested record evidence shows that Schering-Plough's potassium supplement product line, the K-Dur product line, on a combined basis (both K-Dur 10 and 20) make up less than 40 percent of the total prescriptions for potassium in June 1997. *See* CX 20 from August 1997 (38% market share of TRX). Having failed to demonstrate that Schering had monopoly power in June of 1997, Complaint Counsel fail on prong one of Bresnahan's rule. Without even getting to the second and third prong of Bresnahan's test, Complaint Counsel fail to meet the Bresnahan test for determining whether the agreement was anticompetitive as of June 1997.

### B. Complaint Counsel Have Failed To Prove That There Was A Disguised Payment To Delay Upsher-Smith's Entry

As to the third part of the Bresnahan test, Complaint Counsel's case rests on a disguised payment for delay, by means of an overpayment by Schering-Plough for certain licensing and supply rights. But Complaint Counsel did not provide evidence of any such overpayment in their case in chief.

#### 1. Complaint Counsel's Valuation Evidence Fails To Prove That There Was "Net Positive Value" Paid To Upsher-Smith Under The Bresnahan Test

Complaint Counsel's case rests on the premise that "net positive value" was paid to Upsher-Smith in June 1997. *See* Tr. 655:15-656:6 (Bresnahan stating that "the payment can take any form as long as it is a ***net positive value*** to the entrant.") (emphasis added); Tr. 660:20-24; Tr. 663:8-12 (the value was examined about the time of the agreement). Complaint Counsel acknowledged that proof of payment for delay was critical to their success at trial. *See* Trial

Brief at 34 (agreeing that in order to prevail at trial they must prove a payment for delay). Complaint Counsel, however, have adduced no evidence that Schering actually ***overpaid*** Upsher-Smith for the licenses and supply agreements in the June 17, 1997 Agreement. The only evidence Complaint Counsel proffered on the "net positive value" element of the Bresnahan Test was Dr. Levy's opinion testimony that the value of Niacor-SR did not justify a "$60 million noncontingent" payment. This isolated opinion, however, falls short of establishing a payment for delay.

First, Levy used the wrong valuation yardstick. The Bresnahan test measures the reasonableness of the Agreement as of June 1997, and in particular, measures the "net positive value" to the generic firm as of June 1997. *See* Tr. 659:17-24; Tr. 660:14-661:2.[13] And Bresnahan testified that Schering's promise to receive three payments was worth $54.5 million in June 1997 to Upsher-Smith. *See* Tr. 662:22; 663:5. But Levy never used the June 1997 value of the payment stream to Upsher-Smith, $54.5 million, as a yardstick to assess the value of Niacor SR. Levy used the $60 million nominal figure. *See* Tr. 2133:17-2134:8. Levy never measured the value of the Niacor SR license as of June 1997, *see* Tr. 2057:25-2058:2, and he expresses an opinion only in terms of $60 million.

Second, and even more fundamentally, Levy did not compute any quantitative value for the Niacor SR license, or for any of the other licenses in the June 1997 Agreement. *See* Tr. 2057:25-2058:2; 2058:10-12; 2058:2-10; 2059:17-20. Thus, Levy could not testify whether Niacor SR was worth $0, $10 million or $100 million. *See* Tr. 2063:18-20; 2064:23-25. Unlike Schering, he simply did not compute a June 1997 value for Niacor SR at all. *See* Tr. 2064:23-25.

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[13] Levy's hindsight methodology is not legally sufficient to second-guess the June 1997 Agreement, because the relevant inquiry occurs as of June 1997.

Further, Levy's very limited valuation work was done only with respect to one of the six product ***license agreements***, Niacor SR. Bresnahan himself conceded that all five of the other pharmaceutical products for which Schering licensed rights in non-NAFTA countries had positive value as of June 1997: Prevalite, (Tr. 953:13-14), Pentoxifylline (Tr. 956:5-6), Klor Con 8 (Tr. 951:6-8), Klor Con 10 (Tr. 951:6-8), and Klor Con M20 (Tr. 951:6-8). Despite Bresnahan's concession, Levy again did not value any of the other five pharmaceutical products that were contained in the June 1997 license agreements, as he admitted. *See* Tr. 2064:1-25 (failure to quantify a value for Prevalite, Pentoxifylline, Klor Con 8, Klor Con 10 and Klor Con M20 licenses at $0, $10 million or $100 million).

Moreover, despite Bresnahan's clear concession that each of the six product ***supply agreements*** had some positive value as of June 1997: Niacor SR, (Tr. 948:19-25), Klor Con 8, (952:4-17) Klor Con 10, (952:4-17) Klor Con M20 (952:4-17), Pentoxifylline (956:22-24), Prevalite (954:19-21), Levy admitted that he failed to examine or value any of the six supply agreements contained in the June 1997 Agreements. *See* Tr. 2060:12-20. In short, Levy's failure to perform a valuation analysis means that as a matter of logic (even crediting all of his testimony for purposes of this motion — in itself a tremendous leap of faith), the Levy opinion fails to establish a prima facie case that the June 1997 Agreement was not worth $54.5 million in June 1997. Having used the wrong yardstick, having failed to provide an alternative computation of value, and having failed to even evaluate all of the consideration that Schering received, the Levy valuation testimony does not support the conclusion that Upsher-Smith was overpaid in June 1997 by Schering.

### 2. Complaint Counsel Have Failed To Prove That The "Payment" Was Intended "To Delay" Upsher-Smith's Entry Under The Bresnahan Test

Part 3 of Bresnahan's Test requires proof of a payment made "to delay" Upsher-Smith's entry onto the market. *See supra* at 2. No evidence establishes that Schering-Plough actually made a payment "to delay" Upsher-Smith's entry.

Professor Bresnahan admitted that he did not assess anticompetitive intent. *See* Tr. 1028:12-24. Dr. Levy similarly conceded that he had not opined about the motives of Upsher-Smith and Schering in the payment of the alleged $60 million. *See* Tr. 1888:7-14. In the case in chief, Complaint Counsel have presented no evidence that demonstrates that executives who negotiated the settlement agreement had any anticompetitive intent to delay generic entry. *See* Tr. 970:20-25, 971:1-7 (Bresnahan admitted there was no evidence of furtive conduct by any executive of Schering or Upsher-Smith).

There was evidence in the case in chief to the contrary. In Schering's Board of Directors' Report, Schering states its intention that the licensing agreement "should stand on its own merit independent of the settlement." CX 338 (Schering Board of Directors Presentation). Bresnahan, Complaint Counsel's expert document reader, admitted that he was unable to assess the credibility of such a statement, even though he completely ignores it in his report. *See* Tr. 973:14-974:19.

Further, the Board of Directors' Report computes a net present value of more than $200 million for Niacor SR alone and discusses the other products for which license and supply rights are being obtained. CX 338. Bresnahan admitted that he does not dispute ***any*** of the figures that appear in Schering's Board valuation. *See* Tr. 975:13-976:21. Bresnahan does not contend that any figure in the Schering Board presentation is "false" or "fraudulent." *See* Tr. 976:22-977:1. Bresnahan further concedes that he is unable to assess the credibility of any witnesses at the

Board of Directors meeting, even though Schering's intent is an important part of the competitive analysis under rule of reason. *See* Tr. 974:17-19. Such a failure by Bresnahan, who had access to all of the documents of both companies and third parties, to consider intent in his analysis highlights Complaint Counsel's lack of proof.[14]

### C. Complaint Counsel Have Failed To Prove That Actual Injury To Competition Occurred And That There Was A Net Anticompetitive Effect Under The Rule Of Reason

Where, as here, there are admittedly pro-competitive aspects and no substantial prior judicial experience, *per se* treatment is not warranted. *See State Oil v. Kahn*, 522 U.S. 3, 10 (1997) (holding 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***") (emphasis added); *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 50 (1977) (citations omitted) (stating that the *per se* rule should only apply to conduct that has a "pernicious effect on competition" and "lack[s] any redeeming value"); *United States v. Topco Assoc., Inc.*, 405 U.S. 596, 607-08 (1972) (finding that the *per se* rule is only appropriate where courts have accumulated "considerable experience" and where the conduct inevitably results in a finding of anticompetitive effects).

Complaint Counsel's own economic expert conceded that the Agreement had "pro-competitive" aspects including: providing Upsher certain date for entry of Klor Con 20 (Tr. 906:9-15), the expanding of Upsher's products in the world market (Tr. 963:20-25, 964:1-7) and the avoiding of the complete exit of Upsher from entering the market with a generic if they had lost the litigation (Tr. 666:25, 667:1-4). Without clear indication from court precedent that the settlement at issue is "manifestly anticompetitive" and "always or almost always tends to restrict

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[14] Complaint Counsel similarly have failed to establish any anticompetitive intent in respect of either a) the 180-day Hatch-Waxman Act, *see supra* section II; or b) the "other tablet" language, *see infra* section III.

competition and decrease output," a court will apply the rule of reason analysis, in order to weigh all competitive effects. *See Business Elec. Corp. v. Sharp Elec. Corp.*, 485 U.S. 717, 723 (1988).

Under the rule of reason, courts apply a three-part test:

> "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 v. F.T.C.*, 224 F.3d 942, 947 (9th Cir. 2000) (on remand from the U.S. Supreme Court) (emphasis added).

### 1. Complaint Counsel Have Not Adduced Any Proof Of Actual Delay Or Other Adverse Competitive Effect

Complaint Counsel have introduced no evidence that would suggest that any earlier entry date actually could have been achieved by Upsher-Smith in its negotiation with Schering-Plough. In fact, to the contrary, Professor Bresnahan testified that, despite his exhaustive review of the record, he is unaware that Schering-Plough would ever have been willing to offer Upsher-Smith an entry date earlier than September 1, 2001 — the latest date that the June 1997 Agreement provides for Upsher-Smith's licensed entry into the sale of microencapsulated potassium tablets. *See* Tr. 901:21-24).[15] There is no proof that Schering would have been willing to permit an earlier settlement than September 1, 2001. *See* Tr. 901:21-24, 902:10-16 (Bresnahan concluding that he has not seen any evidence that Schering was willing to settle any earlier than September 1, 2001). Complaint Counsel's expert Bresnahan did not prove that any other settlement could have occurred. *See* Tr. 1008:18-25, 1009:1-3 (Bresnahan was unable to articulate another possible settlement that the parties could agree to). There is also no evidence that Schering-

[15] Indeed, the June 1997 Agreement actually provides for an entry date earlier than September 1, 2001, if Schering's Warrick Division introduces a generic version of K-Dur earlier or licenses a trial earlier than September 1, 2001. *See* CX 348 at Exh. A at i, ¶ 3 (USL03186).

Plough, which had agreed to take more than 60 months off the patent, was willing to take another day off the patent. *See* Tr. 899:8-14 (Bresnahan recognizing that the settlement permitted entry 60 months before the end of the patent). Consumers got the certain benefit of an Upsher-Smith entry no later than September 1, 2001, as opposed to the uncertain outcome — not proven in the case-in-chief — that would risk an entry no earlier than September 5, 2006.[16] If Upsher-Smith "had lost the patent lawsuit, they would have ***disappeared*** as a potential entrant." Tr. 666:25-667:4.

Furthermore, had the patent litigation continued, there is no proof that the trial, appeal, manufacturing ramp-up and FDA regulatory approvals would have been secured prior to September 1, 2001. Nor did Bresnahan examine the opportunity costs to Upsher-Smith of the monthly drain of future litigation against marketing, R&D and other activities; Upsher-Smith might well have concluded that it was simply too expensive to continue the litigation vs. other uses of capital within the firm. *See* Tr. 1007:9-14 ("I don't know whether it would be in [Upsher's] interest to continue [the lawsuit]"). None of these possibilities were modeled by Professor Bresnahan, or any other Complaint Counsel witness. *See* Tr. 904:7-12 (Bresnahan admitted that he had not modeled how long Schering could have drawn out the litigation).

Bresnahan's direct testimony did not discuss any of the specific events that had occurred in the patent litigation before it was settled, the duration of the litigation, the cost in management distraction for Upsher-Smith, the monthly expense of the litigation or any of the background events that led to the June 1997 Settlement Agreement. Complaint Counsel's expert simply

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[16] In fact, if Upsher-Smith had lost the patent litigation or abandoned the litigation, and thus had not settled the litigation, Professor Bresnahan acknowledged that consumers would not receive the benefit of competition from Upsher-Smith's Klor Con M20 product until 2006 due to Schering's patent. *See* Tr. 896:25, 897:1-17. Moreover, the settlement offered the certainty of competition in a relatively short amount of time, rather than indefinitely or only after 2006. *See* Tr. 906:9-15 (Bresnahan recognized that the settlement offered Schering a certain date for entry of Klor Con 20).

failed to conduct the type of detailed market-specific analysis, examining the context of the agreement in question, that is required under the rule of reason. *See United States v. Topco Associates*, Inc., 405 US 596, 607 (1972) (stating "[a]n analysis of the reasonableness of particular constraints includes consideration of the facts peculiar to the business in which the restraint is applied, the nature of the restraint and its effects, and the history of the restraint and the reasons for its adoption.") (citing *Chicago Board of Trade v. United States*, 246 US 231, 238 (1918).

In short, Complaint Counsel have rested without demonstrating that there existed a better scenario for consumers than the more than 5 year reduction in the life of the '743 patent, a result that Bresnahan admits took more than half off the chronological life (55%) of the '743 patent. *See* Tr. 895:2-19.

Complaint Counsel also has not presented any rigorous quantitative data from the potassium chloride market. *See California Dental Ass'n v. F.T.C.*, 224 F.3d at 957 (stating that, "[o]ur case law usually requires the antitrust plaintiff to show some relevant data from the precise market at issue in the litigation . . . "); Tr. 810:12–853:25 (Bresnahan conceding that Klor Con 10 and 8 compete with K-Dur 20, and that he had not done any comparative quantitative analysis). Furthermore, Complaint Counsel has not made any attempt to quantify **any increase in price** in the market over the competitive level. *See id.* at 957 (finding that the F.T.C. had "failed to demonstrate substantial evidence of a net anticompetitive effect" in part because the F.T.C. "never quantified any increase in price or reduction in output" in the relevant market. *See* Tr. 811:24-812:5 (Bresnahan admitting that he did not conduct an econometric analysis of a potential price increase).

### 2. Complaint Counsel Have Not Adduced Any Proof Of A *Net* Anticompetitive Effect, After Weighing The Pro- And Alleged Anti-Competitive Elements Of The Agreement

Complaint Counsel have failed to prove that the settlement agreement had a ***net*** anticompetitive effect on the potassium market, after weighing the pro- and anticompetitive aspects of the June 1997 Agreement. Complaint Counsel have not proven that the settlement agreement "engendered a net harm to competition," as required under a rule-of-reason analysis. *See California Dental Ass'n v. F.T.C.*, 224 F.3d 942, 957 (9th Cir. 2000) (finding that the F.T.C. failed to demonstrate substantial evidence of a net anticompetitive effect). The hallmark of the rule of reason analysis is an on-balance weighing of all effects of the alleged restraint. *See Business Elec. Corp. v. Sharp Elec. Corp.*, 485 U.S. 717, 723 (1988) (stating that the court applies the rule of reason to weigh the all competitive effects); *California Dental Ass'n v. F.T.C.*, 526 U.S. 756, 781 (1999) (remanding the case to the Ninth Circuit to weigh the effects of the restraint).

But Complaint Counsel's expert Bresnahan did not perform such a weighing. The Bresnahan test is categorical, prohibiting any agreement that contains a "net positive payment" to the generic firm. Professor Bresnahan did not model for positive net effects of the settlement. Such a weighing is critical, as here, where Bresnahan acknowledged a number of pro-competitive elements of the June 1997 Agreement. *See* Tr. 906:9-21; 963:20-25; 964:1-7; 986:9-18. His test simply does not weigh them and disregards any benefits where there is "net positive payment."[17]

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[17] And this is not a case where the Agreement itself facially is anticompetitive. Complaint Counsel in their trial brief, Trial Brief at 43, and Professor Bresnahan do ***not*** suggest that patent infringement settlement agreements are facially anticompetitive because they involve an entry date agreement. If there is no net reverse payment to the entrant, Bresnahan's test does not bar such an entry date agreement, Tr. 936:8-12, even if a ***later*** entry date is agreed to. *See* Tr. 937:9-25, 938:1-9. Further, Bresnahan concedes there is no noted payment for delay. *See* Tr. 968:25-969:10.

## II. Complaint Counsel Have Failed To Establish A Prima Facie Case That The 180-Day Hatch-Waxman Period In Fact Kept Any Firm Off The Market Or That Upsher-Smith Intended To Use The Period To Keep Potential Competitors Off The Market

The Complaint alleges that the June 1997 Settlement Agreement "has the effect of delaying entry into the relevant market by any other potential generic competitor," Compl. ¶ 66, and specifically identifies only Andrx Corporation as the firm that "cannot market its product until Upsher-Smith's 180-day Exclusivity Period has run." Compl. ¶ 62.[18] Based on these allegations, the Court denied respondents' motion to dismiss because whether any firm "was blocked is a disputed factual question," Order dated Oct. 31, 2001 at 10, and because "the start date for triggering the exclusivity period is alleged to have been manipulated by the parties." *Id.* at 9. It remained for Complaint Counsel to prove at trial that the parties engaged in "concerted action to manipulate the trigger date and preserve the exclusivity period." *Id.*

### A. No Evidence Exists That Any Firm Has Actually Been Blocked As A Result Of The June 1997 Agreement

Professor Bresnahan testified that no potential competitors were blocked from entering the alleged product market for K-Dur 20 as a result of the June 17, 1997 Agreement. *See* Tr. 912:12-17 (Bresnahan conceding that he is not aware of any generic entry blocked by the settlement agreement). Indeed, despite the current running of the 180-day period which expires on February 28, 2002, Bresnahan admitted that there are currently three generic 20 mEq potassium tablet products on market: Warrick (Schering), Klor Con M20 (Upsher-Smith), and Qualitest. *See* Tr. 929:14-25. Bresnahan also testified that the change in law regarding 180-day exclusivity was not attributable to Upsher-Smith's or Schering's conduct. *See* Tr. 982:11-25 (Bresnahan acknowledged that neither firm could influence a subsequent change in law).

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[18] The 180-day provision of the Hatch-Waxman Act is attached as Appendix A to this Memorandum of Law.

The Complaint only alleges that one firm — Andrx — was blocked by Upsher-Smith's exclusivity. Compl. ¶¶ 61-62. [

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**B. There Is No Proof That Upsher-Smith Intended To Manipulate The 180-Day Period, As Its Entitlement To Exclusivity Was "Substantially Uncertain" At The Time Of The June 1997 Agreement**

Because Complaint Counsel's expert witness Joel Hoffman testified it was "substantially uncertain" as a matter of FDA law whether or not Upsher-Smith would have been eligible for 180-day exclusivity on June 17, 1997, Upsher-Smith could not have formed the specific intent to manipulate the exclusivity period and conspire with Schering to maintain Schering's monopoly. 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 at the time of the conduct negates the element of "specific intent." *See, e.g., James v. United States*, 366 U.S. 213 (1961); *AFL-CIO v. Fed. Election Comm'n*, 628 F.2d 97, 101 (D.C.

Cir. 1980) (vacating civil penalties where the legality of defendant's conduct "was hitherto untested by any sort of tribunal").[19]

Mr. Hoffman testified that based on 38 years of FDA legal expertise, had he been retained by Upsher-Smith as of June 1997, the date of the Agreement, he would have had "no idea" what the state of the law was with respect to the 180-day exclusivity period in June 1997. *See* Tr. 2322:22-2323:15. Hoffman testified that there was "substantial uncertainty" in the application of the Hatch-Waxman Act at that time. *See* Tr. 2193:20-25. And in January 1998, Upsher-Smith's right to 180-day exclusivity was "equally or more uncertain" than "substantial uncertainty." *See* Tr. 2257:6-13 ("The uncertainty in my opinion was equal or great to that on June 17th, '97"); 2194:4-9.

Most fundamentally, there is no evidence that Upsher-Smith or Schering ever ***actually considered*** the Hatch-Waxman Act's 180-day provision as applying to them. Professor Bresnahan admitted that any subsequent exclusivity that Upsher-Smith received was pursuant to a change in law after the settlement agreement and was not considered during negotiation of the settlement agreement. *See* Tr. 982:11-25. In fact, nowhere in Schering or Upsher-Smith documents or in the settlement agreement is the 180-day exclusivity mentioned as a consideration in creating the settlement agreement. *See* Tr. 914:23-915:9 (Bresnahan acknowledging that there is no reference to the 180-day exclusivity or Hatch-Waxman in the agreement); *See* Tr. 915:21-25, 916:1-8, 917:5-11 (Bresnahan noting that there was no mention of 180-day exclusivity in any of the memos or documents he reviewed from Upsher-Smith or Schering-Plough).

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[19] With "substantial uncertainty" in the law, as confirmed by Complaint Counsel's expert, it is impossible for Upsher-Smith to have formed even the general intent required under the rule of reason. *See supra* Section II.

### C. Under Current Interpretation Of The Hatch-Waxman Act, Upsher-Smith Would Have Been Entitled To 180-Day Exclusivity Under Any Settlement Or Litigation Result

Complaint Counsel failed to establish that any other scenario exists — full-blown patent litigation or another realistic patent settlement — that would benefit consumers as much as the June 1997 Agreement. But even if another scenario had been presented in Complaint Counsel's case in chief, according to Joel Hoffman, ***all scenarios*** under current FDA law would have entitled Upsher-Smith to exclusivity.

Mr. Hoffman testified that, under present law, if Upsher-Smith had litigated and won in its patent suit, it would have been entitled to 180-day exclusivity. *See* Tr. 2355:21-2356-1. Further, in direct contradiction of Paragraph 66 of the Complaint, Mr. Hoffman testified, based on current law, that if Upsher-Smith litigated and lost its suit to Schering, Upsher-Smith would have been barred from marketing until September 5, 2006 and at that time, Upsher-Smith would have been eligible for 180-day exclusivity. *See* Tr. 2367:4-8.

Similarly, in Hoffman's view, marketing by Upsher-Smith under ***any*** settlement agreement would have triggered 180-day exclusivity. *See* Tr. 2381:20-2382:13. If the entry date was September 1, 2002 rather than 2001, the marketing under such an agreement would still trigger the 180 days according to Hoffman. *Id.*; *see also* Tr. 2360:23-2361:3. Bresnahan also conceded that any settlement agreement, followed by marketing, would trigger the 180 days. *See* Tr. 1007:21-22 ("any settlement? Well would have triggered it [180 days] as much as this one did."). Mr. Hoffman's opinion is not tied to the specific provisions of the Upsher-Smith/Schering settlement because Mr. Hoffman never reviewed the agreement — his opinion is generic to any settlement agreement. *See* Tr. 2324:6-10 (admitting that he did not review the

settlement agreement). Regardless of the settlement agreement, under current law, Upsher-Smith would be entitled to 180-day exclusivity.[20]

## III. Complaint Counsel Have Failed To Establish That The "Any Other Sustained Release Tablet" Clause Has Restricted Competition

Complaint Counsel argue that Paragraph 3 of the June 1997 Agreement restrained Upsher-Smith from developing "another generic version of Schering's K-Dur 20. C.mpl. at ¶ 49; see also Compl. ¶ 44 ("Upsher-Smith agreed not to enter the market . . . with any other generic version of K-Dur 20"). Paragraph 3 reads: "Upsher-Smith agrees that it will not market in the United States its Klor Con M20 potassium chloride product ***or any other sustained release microencapsulated potassium chloride tablet*** prior to September 1, 2001." CX 348 (Settlement Agreement, June 17, 1997) (emphasis added). At trial, Complaint Counsel's own witness admitted that this "any other sustained release . . . tablet" language has not restricted competition.

### A. Complaint Counsel Have Failed To Prove That Any Upsher-Smith Products Were In Fact Blocked From Entering The Market

Complaint Counsel's expert, Professor Bresnahan, admitted that there is no evidence that this restriction blocked any future Upsher-Smith product from entering the market. *See* Tr. 984:8-12 (Bresnahan noted he was unable to identify any Upsher-Smith product that was specifically blocked by the language). Bresnahan also confirmed that there is no evidence that Upsher-Smith believed that another product besides Klor Con M20 was being described by the language in paragraph 3 of the settlement agreement. *See* Tr. 987:7-12. Bresnahan did not

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[20] Mr. Hoffman's testimony demonstrated vividly that not only was there substantial uncertainty in June 1997, but that the uncertainty and vagaries of the complex Hatch-Waxman Act have continued to the present day. Mr. Hoffman agreed with the FDA's March 2000 guidance to industry that described recent court decisions as adding "considerable uncertainty to FDA's implementation of ANDA approval and 180-day generic drug exclusivity programs." *See* Tr. 2364:8-14; CX 598. Obviously, even to a 38-year veteran of FDA law, the 180-day statute and the application are complex. *See* Tr. 2335:3-4 ("both the statute and its application are complex"); *see* Tr. 2334:23-2335:2.

consult a biochemist, pharmacologist, or independent patent expert to assess whether another "generic" sustained release microencapsulated potassium chloride was possible or viable, as a matter of chemistry, that would not infringe Schering's '43 patent. *See* Tr. 985:4-16. Finally, with reference to this language, Bresnahan conceded that he had not examined Upsher-Smith's product pipeline between 1997 and 2001. *See* Tr. 984:13-24. No other witness was proffered on this point by Complaint Counsel.

### B. Complaint Counsel Have Failed To Prove That Upsher-Smith Contemplated That This Clause Covered Any Other Products Besides Klor Con M20

Bresnahan conceded that he had not found any evidence that anyone at Schering-Plough or Upsher-Smith had any other product in mind other than the Klor Con M20 product at the time of the agreement:

> Q. And you have no evidence that Schering-Plough, as you sit here today, had any product in mind other than the Klor Con M20 product. Isn't that correct?
>
> A. That's right too.
>
> Q. And you have no evidence as you sit here today that Upsher-Smith had any other product in mind other than Klor Con M20. Isn't that correct?
>
> A. Yes.

Tr. 984: 16-24. *See also* Tr. 987: 8-16 (Bresnahan has no evidence that the language refers to any product other than Klor Con M20).

### C. This Clause Is Conceded To Be An Ancillary Restraint

The language of paragraph 3 is standard in settlement agreements. It falls within the long-recognized doctrine of ancillary restraints that permits covenants not to compete that further procompetitive objectives. *See United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 282 (6th Cir. 1898), *aff'd*, 175 U.S. 211 (1899) (public interest as well as private benefit underlay the

tolerance of the ancillary restraint); *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 224 (D.C. Cir. 1986) ("The ancillary restraint is subordinate and collateral in the sense that it serves to make the main transaction more effective in accomplishing its purpose."); *see also United States v. Columbia Pictures Corp.*, 189 F. Supp. 153, 178 (S.D.N.Y. 1960).[21]

Professor Bresnahan concedes that the ancillary restraint would ***not*** be anticompetitive, if the license agreement were considered procompetitive. *See* Tr. 988: 5-13. Bresnahan also admitted that the language of paragraph 3 is not independently anticompetitive. *See* Tr. 990:23-991:8 ("I could imagine that this would be used to enforce a non — a pro-competitive agreement and that this — if the rest of the agreement were pro-competitive and if there were no other tablets, that this wouldn't render it necessarily anti-competitive").

## IV. Complaint Counsel Have Failed To Establish A Prima Facie Case Of Conspiracy To Monopolize Under Count IV Of The Complaint

Conspiracy to monopolize consists of four elements: (1) a combination or conspiracy to monopolize; (2) overt acts done in furtherance of the combination or conspiracy; (3) a specific intent to monopolize; and (4) an appreciable effect on interstate commerce. *See TV Communications Network, Inc. v. TNT, Inc.*, 964 F.2d 1022, 1026 (10th Cir. 1992). Complaint Counsel have failed to establish a prima facie case of conspiracy to monopolize. Complaint Counsel have presented ***no evidence*** of a conspiracy or specific intent to monopolize. To the contrary, the live witnesses in Complaint Counsel's case-in-chief have established that Upsher-Smith ***affirmatively*** sought to disrupt Schering's sales of potassium supplements at all relevant times, and thus could not have conspired with Schering to monopolize.

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[21] Under the rule of reason analysis, ancillary restraints are "reasonably necessary" to accomplishment a contract's efficiency-enhancing purpose – preventing an alleged infringer from repeatedly interfering with the patent owner's rights. *See Law v. NCAA*, 134 F.3d 1010, 1019 (10th Cir. 1998) (inquiring whether the challenged conduct is "reasonably necessary to achieve legitimate objectives"); *Orson, Inc. v. Miramax Film Corp.*, 79 F.3d 1358, 1367-68 (3d Cir. 1996) (inquiring whether the restraint is "reasonably necessary to achieve the stated objective"); *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993) (same).

### A. Complaint Counsel Have Not Presented Any Evidence Of Specific Intent To Monopolize

To prove a conspiracy to monopolize, 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, 541-42 (7th Cir. 1986). A firm is said to have acted with specific intent only if it "consciously desired" the result prohibited by law. *See United States v. Gracidas-Ulibarry*, 231 F.3d 1188, 1196 (9th Cir. 2000) (citing, *inter alia*, *United States v. Gypsum*, 438 U.S. 422, 444 (1978)). Thus, Complaint Counsel must prove that Upsher-Smith "***consciously desired***" that Schering monopolize the relevant market. *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]"). As demonstrated below, Complaint Counsel have not, and cannot, show that Upsher-Smith consciously desired that Schering monopolize the potassium supplement market.

Specific intent is a highly demanding evidentiary standard. Indeed, it is the reason why most conspiracy-to-monopolize claims fail as a matter of law.[22] As Judge Motz recently

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[22] *See, e.g., Aquatherm Inds., Inc. v. Florida Power & Light Co.*, 145 F.3d 1258, 1261-62 (10th Cir. 1998); *Le Baud v. Frische*, 156 F.3d 1243, 1998 WL 547504, *8 (10th Cir. 1998) (Table); *Levine v. Central Florida Med. Affiliates, Inc.*, 72 F.3d 1538, 1556 (11th Cir. 1996); *Christofferson Dairy, Inc. v. MMM Sales, Inc.*, 849 F.2d 1168, 1174-75 (9th Cir. 1988); *Belfiore*, 826 F.2d at 183; *Int'l Distrib. Ctrs.*, 812 F.2d at 796; *North Miss. Communications, Inc. v. Jones*, 792 F.2d 1330, 1336 (5th Cir. 1986); *Great Escape*, 791 F.2d at 541-42; *American Key Corp. v. Cole Nat'l Corp.*, 762 F.2d 1569, 1579 (11th Cir. 1985); *Ass'n for Intercollegiate Athletics for Women v. NCAA*, 735 F.2d 577, 586 n.13 (D.C. Cir. 1984); *Olsen v. Progressive Music Supply, Inc.*, 703 F.2d 432, 438 (10th Cir. 1983); *Richter Concrete Corp. v. Hilltop Concrete Corp.*, 691 F.2d 818, 827 (6th Cir. 1982); *Morton Buildings of Nebraska, Inc. v. Morton Buildings, Inc.*, 531 F.2d 910, 919 n.12 (8th Cir. 1976); *Westinghouse Elec. Corp. v. CX Processing Labs., Inc.*, 523 F.2d 668, 676 (9th Cir. 1975); *Sulmeyer v. Coca Cola Co.*, 515 F.2d 835, 851 (5th Cir. 1975); *Hudson Valley Asbestos Corp. v. Tougher Heating & Plumbing Co., Inc.*, 510 F.2d 1140, 1144 (2d Cir. 1975); *Chisholm Brothers Farm Equipment v. Int'l Harvester Co.*, 498 F.2d 1137, 1145 (9th Cir. 1974); *Monsanto Co. v. Trantham*, 156 F. Supp. 2d 855, 865 (W.D. Tenn. 2001); *In re Microsoft Corp. Antitrust Litig.*, 127 F. Supp. 2d 728, 733 (D. Md. 2001); *Lamminen v. Cloquet*, 987 F. Supp. 723, 733 (D. Minn. 1997); *HTI Health Servs., Inc. v. Quorum Health Group, Inc.*, 960 F. Supp. 1104, 1139-40 (S.D. Miss. 1997); *AD/SAT v. Associated Press*, 920 F. Supp. 1287, 1318 (S.D.N.Y. 1996); *Black and Decker, Inc. v. Hoover Serv. Ctr.*, 765 F. Supp. 1129, 1141 (D. Conn. 1991); *Bi-Rite Oil Co., Inc. v. Indiana Farm Bureau Cooperative Ass'n, Inc.*, 720 F. Supp. 1363, 1376-78 (S.D. Ind. 1989), *aff'd*, 908 F.2d 200 (7th Cir. 1990); *Genetic Sys. Corp. v. Abbott Lab.*, 691 F. Supp. at

explained, specific intent "signifies something more than willing, voluntary, and knowing participation in the illegal course of conduct that [defendant] is alleged to have pursued." *In re Microsoft Corp. Antitrust Litig.*, 127 F. Supp. 2d 728, 731 (D. Md. 2001). Rather, "[i]t means participating in that course of conduct for the ***specific, shared purpose*** of maintaining" Schering's monopoly. *Id.* (emphasis added) (citing *SuperTurf, Inc.*, 660 F.2d at 1283). *See also Belfiore v. New York Times Co.*, 826 F.2d 177, 183 (2d Cir. 1987) (even if the Times did possess the requisite specific intent to achieve a monopoly, the conspiracy-to-monopolize claim would fail for lack of evidence that the intent was shared with another party); *Int'l Distrib. Ctrs., Inc. v. Walsh Trucking Co., Inc.*, 812 F.2d 728, 796 (2d Cir. 1987) (conspiracy to monopolize requires "a ***plurality of actors sharing***" specific intent) (emphasis added); *Building Ind. Fund v. Local Union No. 3*, 992 F. Supp. 162, 186 (E.D.N.Y. 1996) ("The essence of a conspiracy is not simply a commonality of interest. It involves an agreement by two or more people to accomplish a ***specific illegal objective***") (emphasis added).

The record is bereft of evidence that Upsher-Smith shared the specific intent to further Schering's alleged monopoly in the sale of K-Dur 20, the only product sold in Complaint Counsel's 20mEq potassium chloride market. To the contrary, the evidence demonstrates Upsher-Smith's intent to promote sales of Upsher-Smith's Klor Con potassium chloride products — products that compete vigorously with Schering's K-Dur 20 product. This evidence underscores the implausibility of Complaint Counsel's conspiracy claim. *See TV Communications Network*, 964 F.2d at 1026-27 (holding that cable operators could not have

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(continued)

407, 421-22 (D.D.C. 1988); *Drs. Steuer and Latham, P.A. v. Nat'l Med. Enterprises, Inc.*, 672 F. Supp. 1489 (D.S.C. 1987), *aff'd*, 846 F.2d 70; *Robert's Waikiki U-Drive, Inc. v. Budget Rent-A-Car Sys., Inc.*, 491 F. Supp. 1199 (D. Hawaii 1980).

specific intent to conspire with TNT where such a conspiracy would be contrary to the interests of the cable operators).[23]

Complaint Counsel's expert witness, Professor Bresnahan, provided considerable testimony regarding Upsher-Smith's aggressive marketing of its potassium products ***against Schering's K-Dur 20.*** Bresnahan acknowledged that Upsher-Smith had an avowed marketing strategy of encouraging doctors to substitute two Upsher-Smith Klor Con 10 tablets for one Schering K-Dur 20 tablet. *See* Tr. 856: 4-12, 19-23. Similarly, Bresnahan recognized that by highlighting economic savings to consumers, Upsher-Smith had pitted its own Klor Con 10 against Schering's K-Dur 20. *See* Tr. 858: 9-13, 860: 23-25, 861: 1-17; *see* Tr. 862: 3-25, 863: 1-5. Thus, not only have Complaint Counsel failed to counter the evidence of Upsher-Smith's aggressive competition with Schering, but their own expert demonstrated that Upsher-Smith consciously sought to disrupt the sale of K-Dur throughout the relevant time period. Moreover, Professor Bresnahan recognized that there had been no evidence of collusion between Schering-Plough and Upsher-Smith with respect to their Klor Con 10 and K-Dur 20 products. *See* Tr. 675:23-25, 676:1.

Bresnahan expressly noted the absence of any secretive behavior, as existed in the Phases of the Moon price-fixing conspiracy. *See* Tr. 1057:9-27, 1058:1-25, 1059:1 (Bresnahan admitting that there was no "furtive conduct" in this case). The executives did not behave as if they had something to hide: Bresnahan acknowledged that there were no secret meetings, no phone calls to executives' homes, and no destruction of documents. *See* Tr. 1058:23-1059:1 (Q. Did any of

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[23] In fact, where, as here, there are legitimate business justifications for the conduct, such justifications negate the existence of specific intent. *See Great Escape, Inc.*, 791 F.2d at 541; *Assoc. for Intercollegiate Athletics*, 735 F.2d at 585 n.11; *Sulemeyer*, 515 F.2d at 851; *Bi-Rite Oil Co.*, 720 F. Supp. at 1378. For example, Professor Bresnahan testified to some of the "pro-competitive aspects" of the June 1997 settlement agreement, including: expanding the reach of Upsher-Smith's products into the world market, *see* Tr. 963:20-25, 964:1-7; avoiding legal fees, *see* Tr. 993:17-994:8; and obtaining a date certain for the entry of Klor Con 20, *see* Tr. 906:9-15.

those things happen in this case, sir? A. Not to my knowledge"). Instead, far from furtive conduct, the June 17, 1997 Agreement was premised on the final approval and review of the entire Board of Directors of Schering-Plough. *See* Tr. 1058:12-18. These factors indicate that the participants believed their actions were proper and there was not the "remotest connection" with the furtive, secretive behavior of the executives in the Phases of the Moon conspiracy. *See* Tr. 1058:23-25, 1059:1. In short, Complaint Counsel's case in chief presents no evidence of conspiracy.[24]

**B. Complaint Counsel Have Not Presented Any Evidence Of A Conspiracy**

A conspiracy to monopolize claim requires some evidence of a conspiracy. *See TV Communications Network*, 964 F.2d at 1026 (first element of conspiracy to monopolize is "a combination or conspiracy"); *Mathias v. Daily News, L.P.*, 152 F. Supp. 2d 465, 484 (S.D.N.Y. 2001) (dismissing allegation of conspiracy to monopolize where "[t]he Court is ***left with no information as to the identities of the co-conspirators***, the nature of their conspiracy, how the participants attempted to accomplish their objective, and what overt acts, if any, they performed towards the fulfillment of their conspiracy") (emphasis added). In this regard, Complaint Counsel are unable to point to any evidence of a conspiracy. Complaint Counsel's expert, Professor Bresnahan, could not identify any furtive conduct that would suggest that any Upsher-Smith or Schering executive believed the agreement was a conspiracy. Indeed, after conducting an extensive review of the record, *See* Tr. 414:22-416:25, Professor Bresnahan was unable to name a single individual who acted in a conspiracy to disguise a payment for delay. *See* Tr.

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[24] A conspiracy is all the more inconceivable in that Schering never believed that it could sell more than 4 out of 10 potassium prescriptions. Instead, all of the record exhibits consistently document that Schering believed it had no more than 40% market share at all relevant times – leading up to the June 17, 1997 Agreement; and documents projecting future market share in 1997 never exceeded 40%. *See* Tr. 743:21-25, 746:1-13. This is independent proof that Schering did not believe that it had a monopoly or was soon likely to have a monopoly in the sale of potassium products; Upsher-Smith could not share an intent to monopolize with a party that believed that it was not likely to have even 50% of the prescriptions for potassium in the US.

970:16; 971:13 (Bresnahan: no view as to whether Schering directors disguised payment for delay; no view of any Schering executive making a disguised payment for delay; no member of Upsher-Smith Board of Directors or Upsher-Smith executives having disguised a payment for delay).

## V. Complaint Counsel Have Failed To Establish A Prima Facie Case That The Settlement Agreement Extends The '743 Patent

It is undisputed that Schering has been granted by the U.S Patent and Trademark Office the '743 patent. Compl. ¶34. The '743 patent expires on September 5, 2006. Compl. ¶ 34; *see* Tr. 892:14-16 (Bresnahan: '743 patent expires in September, 2006). The '743 patent is presumed valid by law. *See* 35 U.S.C. § 282 ("A patent shall be presumed valid."). Under the patent, Schering has the absolute right to exclude others who seek to market a product that infringes their patent through September 5, 2006. *See United States v. United Shoe Mach. Co.*, 247 U.S. 32, 57 (1918). Complaint Counsel have rested their case, neither challenging the validity of the '743 patent, nor proving that Upsher-Smith did not infringe the '743. *See, e.g.*, Tr. 670:12; 671:5 (Bresnahan acknowledges the patent and does not contest validity).

As exception to the antitrust laws, U.S. patent law grants lawful monopolies to patent holders within the four corners of the patent. *See, e.g., Dawson Chem. Co. v. Rohm & Hass Co.*, 448 U.S. 176, 215 (1980); *United States v. United Shoe Mach. Co.*, 247 U.S. at 57. As the Supreme Court has held in *Ethyl Corporation* and *General Electric*, license agreements regarding patents are unlawful when the patent holders ***extend*** their lawful "patent monopoly" beyond the lawful power to exclude within the four corners of the claims made in their patent to other products. *See Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 456 (1940) ("The patent law confers on the patentee a limited monopoly . . . [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.") (emphasis added); *United States v. General Electric.*, 272 U.S. 476, 485 (1926) ("It is only when the [patent holder] 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 with the operation of the Anti-Trust Act.") (emphasis added).[25]

In this case, the June 17, 1997 Agreement is a license to Upsher-Smith that does not ***extend*** Schering's lawful patent beyond its four corners; instead it ***shortens*** the life of the '743 patent. *See* CX 348 (June 1997 Settlement Agreement); Tr. 899:8-14, Tr. 895:2-18 (Bresnahan admitted that the agreement permitted entry 60 months before end of the patent, taking about 55% off the life of the patent). The June 17, 1997 Agreement expressly ***permitted*** Upsher-Smith, with certainty, to sell potassium chloride more than 60 months (five years) earlier than the life of the '743 patent, and even earlier if Schering sold a generic before that date.[26] Complaint Counsel have not shown that Schering went beyond the "four corners" of their patent in their license agreement with Upsher-Smith to unlawfully extend the '743 patent. In fact, Bresnahan admits that the June 1997 Agreement shortens the life of the '743 patent. *See* Tr. 899:8-14. Complaint Counsel have failed to establish that the settlement agreement is an unlawful

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[25] The rule of *Ethyl* continues to the present day. *See 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 Inst., Inc.*, 52 F.3d 1026 (1st Cir. 1995); *United States v. CIBA Geigy Corp.*, 508 F. Supp. 1118, 1150-51 (D.N.J. 1976).

[26] Even earlier if Schering introduced a generic for K-Dur 20 before September 1, 2001. CX 348, Agreement, Exhibit A at ¶ 3.

extension of Schering's patent holder rights beyond the four corners of the patent grant, and, thus, Complaint Counsel's claim fails.

## VI. The Relief Requested In The Complaint Is Moot

Finally, the Complaint should be dismissed because the relief sought in the Complaint is now moot. *See United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); *see also Borg-Warner Corp. v. F.T.C.*, 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 F.T.C. staff failed to prove: "a 'cognizable danger of recurrent violation' in this case."). There is now no dispute Upsher-Smith began selling its Klor Con M20 product on September 1, 2001. *See* Tr. 927:22-928:1 (Bresnahan). The 180-day section of the Hatch- Waxman Act has not blocked any firm, see *supra* at Section II, and the 180-day provision will expire without blocking any other potential entrant on February 28, 2002, CX 143; USX 704; Tr. 2350:15-2351:4; 2277:2-3; 923:24-924:8 (J. Hoffman), less than three weeks from today. There is no need for the injunctive relief sought in the Complaint.

## CONCLUSION

Complaint Counsel has not proven that the June 1997 Agreement was "anticompetitive" using Professor Bresnahan's 3-Part Test. Complaint Counsel's case in chief did not provide proof of Counts I and IV sufficient to meet their burden. Thus, they have not established a prima facie case.

Dated: February 15, 2002

Respectfully submitted,

WHITE & CASE LLP

By: _____

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*Attorneys for Upsher-Smith Laboratories, Inc.*

TAB A

# APPENDIX A

## Hatch-Waxman Act Exclusivity Provision

(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after-

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action, described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, § 101 *amending* Section 505 of the Federal Food, Drug, and Cosmetic Act at § 505(j)(4)(B)(iv), 98 Stat. 1585 (1984), *codified at* 21 U.S.C. § 355(j)(5)(B)(iv) (2001).

**UNITED STATES OF AMERICA**
**FEDERAL TRADE COMMISSION**

| | | |
|---|---|---|
| **In the Matter of** | ) | |
| **Schering-Plough Corporation, a corporation,** | ) | |
| **Upsher-Smith Laboratories, Inc., a corporation,** | ) | **Docket No. 9297** |
| **and** | ) | |
| **American Home Products Corporation, a corporation.** | ) | |

**ORDER GRANTING RESPONDENT UPSHER-SMITH'S MOTION TO DISMISS DUE TO COMPLAINT COUNSEL'S FAILURE TO ESTABLISH A PRIMA FACIE CASE**

Upon consideration of Upsher-Smith's Motion to Dismiss for Failure to Establish a Prima Facie Case and Complaint Counsel's Response, it is hereby ORDERED that Upsher-Smith's Motion is GRANTED and the case is dismissed.

Dated: Washington, D.C.
February ___, 2002

D. Michael Chappell
Administrative Law Judge

## CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of February 2002 I caused copies of the foregoing public version of Upsher-Smith's Motion to Dismiss Due to Complaint Counsel's Failure to Establish a Prima Facie Case, and supporting Memorandum of Law to be served upon the following by hand delivery:

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Karen G. Bokat
Federal Trade Commission, Room 3115
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February 15, 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 Respondent Upsher-Smith's Motion to Dismiss Due to Complaint Counsel's Failure to Establish a Prima Facie Case.

We will provide electronic copies of the above-referenced Motion via e-mail.

Sincerely,

Rajeev K. Malik

Enclosures

cc: Laura S. Shores, Esq.
Karen G. Bokat, Esq.
David R. Pender, Esq.