III. CONCLUSIONS OF LAW AND ANALYSIS

A. Jurisdiction

The Complaint charges Schering and Upsher-Smith ("Respondents") with violations of Section 5 of the FTC Act. 15 U.S.C. § 45. Section 5 of the FTC Act gives the Commission jurisdiction to prevent unfair methods of competition by "persons, partnerships, or corporations." 15 U.S.C. § 45. Schering and Upsher-Smith are corporations engaged in the interstate sale of pharmaceutical products. F. 1-9. The Commission has jurisdiction over acts or practices "in or affecting commerce," providing that their effect on commerce is substantial. *McLain v. Real Estate Bd. of New Orleans, Inc.*, 444 U.S. 232, 241-42 (1980); *Hosp. Bldg. Co. v. Trs. of Rex Hosp.*, 425 U.S. 738, 745-46 (1976). Respondents' challenged activities relating to the sale of 20 mEq potassium supplements have an obvious nexus to interstate commerce. F. 1-9. Accordingly, the Commission has jurisdiction over Respondents and the subject matter of this proceeding.

B. Burden of Proof

An initial decision must be supported by "reliable, probative and substantive evidence." Commission Rule 3.51(c), 16 C.F.R. § 3.51(c)(1). "Substantial evidence is more than a mere scintilla. It means such evidence as a reasonable mind would accept as adequate to support a conclusion. It must be of such character as to afford a substantial basis of fact from which the fact in issue can be reasonably inferred. It excludes vague, uncertain or irrelevant matter. It implies a quality and character of proof which induces conviction and makes a lasting impression on reason." *Carlay Co. v. FTC*, 153 F.2d 493, 496 (7th Cir. 1946).

"Counsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto." Commission Rule 3.43(a), 16 C.F.R. § 3.43(a). This is consistent with Section 556(d) of the Administrative Procedure Act ("APA"): "Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. § 556(d). Further, under the APA, an order may not be issued "except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence." 5 U.S.C. § 556(d); *see also In re Standard Oil Co. of California*, 84 F.T.C. 1401, 1446-47 (1974) (finding that under the APA, "[c]omplaint counsel have failed to satisfy their burden to establish by 'reliable, probative and substantial evidence' that the results mentioned in the preceding findings do not support [respondent's] advertising claims").

"[T]he antitrust plaintiff must present evidence sufficient to carry its burden of proving that there was [an anticompetitive] agreement." *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 763 (1984). The government bears the burden of establishing a violation of antitrust law. *United States v. E.I. duPont de Nemours & Co.*, 366 U.S. 316, 334 (1961).

C. Statutory and Regulatory Framework

As set forth in the findings of fact, this case arises from the agreements to settle patent infringement suits brought by Schering, as the manufacturer of the brand name drug K-Dur 20, protected by the '743 patent, against Upsher-Smith and against ESI, as manufacturers of generic drugs, each of which had filed an Abbreviated New Drug Application ("ANDA") with the FDA that contained a Paragraph IV certification that the '743 patent was invalid or not infringed. In order to fully understand the issues involved herein, an overview of the statutory and regulatory framework from which the challenged agreements arose is necessary.

1. Patent Law

Article I, Section 8, Clause 8 of the U.S. Constitution empowers Congress "[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." Patent laws confer upon the patentee the exclusive right to make, use or sell the patented invention during the patent term, and authorize the patentee to exclude others – for example, by the initiation of infringement litigation – from manufacturing, using and/or selling the invention during the patent term. *See* 35 U.S.C. § § 101, 154, 271, 281. (The "Patent Act," 35 U.S.C. § § 1 *et seq.*). The Patent Act also expressly provides that a patent is assignable: the patent owner may "grant and convey an exclusive right under his application for patent . . . to the whole or any specified part of the United States." 35 U.S.C. § 261.

The exclusive rights provided for in patent laws are intended to offer an incentive for investors to take risks in performing research and development. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-81, 484 (1974); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229-30 (1964). The Federal Trade Commission recognizes the role of intellectual property laws in promoting innovation and enhancing consumer welfare.

> The intellectual property laws provide incentives for innovation and its dissemination and commercialization by establishing enforceable property rights for the creators of new and useful products, more efficient processes, and original works of expression. In the absence of intellectual property rights, imitators could more rapidly exploit the efforts of innovators and investors without competitors. Rapid imitation would reduce the commercial value of innovation and erode incentives to invest, ultimately to the detriment of consumers.

U.S. Dep't of Justice and Federal Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* § 1.0 (1995), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,132, at 20,734. The role of patent law in interpreting claims brought under antitrust law is discussed more fully in Section E.4.b. *infra*.

2. The Hatch-Waxman Act

The Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, authorizes the Food and Drug Administration ("FDA") to regulate the marketing and sale of drugs in the United States. 21 U.S.C. §§ 301-397.

An applicant seeking to market a new brand-name drug usually must prepare a New Drug Application ("NDA") for FDA consideration. 21 U.S.C. § 355. Preparing an NDA is frequently a time-intensive and costly process, because among other things, it must contain detailed clinical studies of the drug's safety and efficacy. F.13; *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323, 1325 (Fed. Cir. 2001). The NDA must also include a list of patents which claim the drug. 21 U.S.C. § 355(b)(1). If the FDA approves the NDA, it publishes a listing of the drug and patents on the drug's approved aspects in Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book." 21 U.S.C. § 355(j)(7)(A)(iii).

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Act, which simplified the procedure for obtaining approval of generic drugs. Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. § 355. Under the Hatch-Waxman Act, manufacturers of generic drugs are required to submit an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j). An ANDA offers an expedited approval process for generic drug manufacturers. *Mylan Pharmaceuticals,* 268 F.3d at 1325. Instead of filing a full NDA with new safety and efficacy studies, in an ANDA a generic manufacturer may rely in part on the pioneer manufacturer's work by submitting data demonstrating the generic product's bioequivalence with the previously approved drug. 21 U.S.C. § 355 (j)(2)(A).

When a brand name drug is protected by one or more patents, an ANDA applicant that intends to market its generic product prior to expiration of any patent must certify that the patent on the brand name drug is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the ANDA applicant seeks approval. 21 U.S.C. §§ 355(j)(2)(A)(vii)(I) to (IV). This is known as a "Paragraph IV Certification." If the ANDA contains a Paragraph IV certification, the ANDA applicant must provide notice to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA refers. 21 U.S.C. § 355(j)(2)(B)(i). Upon receiving notice of a Paragraph IV certification, the patent holder has 45 days in which to file a patent infringement suit against the generic manufacturer. 21 U.S.C. § 355(j)(5)(B)(iii). If a patent infringement suit is initiated against the ANDA applicant, the FDA must stay its final approval of the ANDA for the generic drug until the earliest of (1) the patent expiration, (2) a judicial determination of the patent litigation, or (3) the expiration of a 30-month waiting period. 21 U.S.C. § 355(j)(5)(B)(iii).

The statutory framework of the Hatch-Waxman Act creates the potential for costly patent litigation against the generic maker that files a Paragraph IV-certified ANDA. *Mylan Pharms., Inc. v. Thompson*, 139 F. Supp. 2d 1, 7 (D.D.C. 2001), *rev'd on other grounds*, 268 F.3d 1323, 1325

(Fed. Cir. 2001). As an incentive to the first generic maker to expose itself to the risk of costly patent litigation, Hatch-Waxman provides that the first to file a Paragraph-IV certified ANDA ("the first filer") is eligible for a 180 day period of exclusivity ("the 180 day Exclusivity Period"). *Id.*; 21 U.S.C. § 355(j)(5)(B)(iv). That is, during those 180 days, the FDA will not approve any other ANDA for the same generic product until the earlier of the date on which (1) the first firm begins commercial marketing of its generic version of the drug, or (2) a court finds the patent claiming the brand name drug are invalid or not infringed. *Mylan*, 139 F. Supp. 2d at 7; 21 U.S.C. § 355(j)(5)(B)(iv).

The provisions of the Hatch-Waxman Amendments "emerged from Congress' efforts to balance two conflicting policy objectives: to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting on other grounds). Thus, although the declared purpose of this legislation was to "make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962[,]" H.R. Rep. No. 98-857, pt. 1 at 14 (1984), 1984 U.S.C.C.A.N. 2647, Congress expressly recognized the importance of patents.

> Patents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.

H.R. Rep. No. 98-857, pt. 1 at 17, 1984 U.S.C.C.A.N. at 2650. Hatch-Waxman does not compel the holder of a valid patent to relinquish the rights it holds pursuant to that patent prior to the expiration date of that patent.

D. Relevant Geographic and Product Market

The determination of the relevant market is essential to all four violations alleged in the Complaint. Violations One and Two of the Complaint allege that the agreements entered into between Schering and Upsher-Smith and between Schering and AHP (ESI) unreasonably restrained commerce. Complaint ¶ 68, 69. Establishing the relevant market is the starting point in a rule of reason case. *California Dental Ass'n v. FTC*, 224 F.3d 942, 952 (9th Cir. 2000) (proof of relevant geographic and product market necessary for proving injury to competition in rule of reason case); *Stratmore v. Goodbody*, 866 F.2d 189, 194 (6th Cir. 1989) ("The starting point in a rule of reason case is to identify the relevant product and geographic markets."). *See also Twin City Sportservice, Inc. v. Finley & Co., Inc.*, 676 F.2d 1291, 1300 (9th Cir. 1982) ("It is also worth noting that the effort to find a relevant market in this litigation was not performed without purpose. A definition of a relevant market was necessary in order to assess possible Sherman Act violations."). The plaintiff bears the burden of proof of defining the relevant market. *Brokerage Concepts v. U.S. Healthcare, Inc.*, 140 F.3d 494,

513 (3rd Cir. 1998) ("The burden is on the plaintiff to define both components [geographic and product] of the relevant market."); *Double D Spotting Serv. v. Supervalu, Inc.*, 136 F.3d 554, 560 (8th Cir. 1998). As discussed in Section E.4, *infra*, rule of reason analysis is required in this case.

Determination of relevant product market is an especially important inquiry here, where Complaint Counsel's proof that the agreements are anticompetitive is based on a finding that Schering had monopoly power. Complaint Counsel's economic expert, Professor Bresnahan, used a three-part test to determine whether the patent settlements between Schering and Upsher-Smith and between Schering and AHP (ESI) were anticompetitive. F. 414. The three-part test asks:

(1) Does the patent holder have monopoly power?
(2) Is there a threat to that power? The threat need not be a certainty; all that is required is that there be a probability of entry and competition.
(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.

F. 414. If Schering-Plough was not proven to be a monopolist in June 1997, then the first prong of Bresnahan's test would not be satisfied. F. 415-16. Bresnahan also testified that if the patent holder did not have monopoly power, then the agreement would not be anticompetitive. F. 414. ("Only if there's some competition absent, which might happen, can you have an anti-competitive act. If rather than being products with market power or monopoly power they were products that already had enough competition to constrain them, an anti-competitive act couldn't – wouldn't do anything to harm competition."). By making monopoly power an integral part of that expert's testimony, a determination of relevant market is an integral part of Complaint Counsel's case.

In its post trial briefs, Complaint Counsel suggests that it need not define the relevant product market. Complaint Counsel asserts that direct evidence of anticompetitive effects "obviates the need, as a matter of law, to undertake the market definition exercise respondents advance." Complaint Counsel's Post Trial Brief ("CCPTB") at 47. Complaint Counsel argues that the Supreme Court "in *FTC v. Indiana Fed'n of Dentists* . . . made clear that proof of actual anticompetitive effects make market *definition* and market *power* inquiries unnecessary." CCPTB at 83. However, *Indiana Fed'n of Dentists* does not relieve Complaint Counsel of its obligation to *define* the relevant market. Rather, *Indiana Fed'n of Dentists* holds that proof of actual detrimental effects can obviate the need for an inquiry into market *power*. *FTC v. Indiana Fed'n of Dentists* 476 U.S. 447, 460-61 (1986). Complaint Counsel further relies on *Toys "R" Us, Inc. v. FTC*, which holds that, "in a properly defined relevant market," direct evidence of anticompetitive effects is one way to prove market power. 221 F.3d 928, 937 (7th Cir. 2000). Thus, while *Toys R' Us* may relieve Complaint Counsel of proving market power, it does not relieve Complaint Counsel from properly defining the market.

Further, Complaint Counsel's suggestion that, because it has presented evidence of anticompetitive effects, it need not present evidence of monopoly power is illogical. Complaint Counsel cannot prove an effect without first proving by market definition what is claimed to be affected.

Moreover, Complaint Counsel's position that it need not prove or define the relevant market clearly undermines the theory and opinions of Complaint Counsel's expert witness, as his test is premised on finding a monopoly and a threat to the monopoly. *See* CX 1590 (the "three pies" chart); F. 414-16 (if Schering was not a "monopolist" then the Bresnahan Test is not satisfied for anticompetitive agreements).

To prove that the agreements did have anticompetitive effects, Complaint Counsel relied on the testimony of Professor Bresnahan who reached this conclusion based on his finding that Schering was a monopoly and had market power. Without a proper market definition, Bresnahan's opinions are without proper foundation and lose credibility. The case that was brought involved proof of a relevant product market and the expert premised his analysis on the proof of a monopolist within a relevant product market. Accordingly, Complaint Counsel's proof was not built upon a proper determination of market power or monopoly power.

Violations Three and Four of the Complaint allege that Schering has monopoly power in the manufacture and sale of potassium chloride supplements approved by the FDA and the narrower markets contained therein and engaged in conduct to unlawfully preserve such monopoly power and that Schering conspired separately with Upsher-Smith and AHP to monopolize the relevant markets. Complaint ¶ 70, 71. Establishing the relevant market is also necessary to assess whether a defendant possesses monopoly power. *Spectrum Sports, Inc., v. McQuillan*, 506 U.S. 447, 455-56 (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.") (citations omitted); *Walker Process Equip. Inc., v. Food Mach. and Chem. Corp*., 382 U.S. 172, 177 (1965) ("Without a definition of that market there is no way to measure [the respondent's] ability to lessen or destroy competition.").

Complaint Counsel bears the burden to establish the relevant market, which is "an indispensable element of any monopolization case." *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1355 (Fed Cir. 1999); *see Elliot v. United Ctr.*, 126 F.3d 1003, 1003-04 (7th Cir. 1997); *Alcatel USA, Inc. v. DGI Techs., Inc.*, 166 F.3d 772, 781 (5th Cir. 1999); *H.J., Inc. v. Int'l Tel. & Tel.*, 867 F.2d 1531, 1537 (8th Cir. 1989) ("The plaintiff carries the burden of describing a well-defined relevant market, both geographically and by product, which the defendants monopolized."). Complaint Counsel did not meet its burden of establishing the relevant product market.

1. Geographic Market

The relevant geographic market is the region "in which the seller operates, and to which the purchaser can practicably turn for supplies." *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961). Purchasers of potassium chloride supplements in the United States can purchase these products only from manufacturers who market in the United States, and whose products have been approved for sale in the United States by the FDA. F. 26. Schering and Upsher-Smith have FDA approval and do sell their potassium chloride supplements in the United States. F. 25-28. Therefore, the relevant geographic market for assessing the allegations of the Complaint is the United States. F. 25-28

2. Product Market

The Complaint alleges:

> The relevant markets are the manufacture and sale of all potassium chloride supplements approved by the FDA, and narrower markets contained therein, including manufacture and sale of 20 milliequivalent extended-release potassium chloride tablets and capsules.

Complaint ¶ 21. At trial, Complaint Counsel's position was that the relevant product market is 20 milliequivalent potassium chloride tablets and capsules. F. 30.

Respondents argue that the evidence does not support Complaint Counsel's alleged product market of 20 mEq sustained release potassium chloride tablets.

The greater weight of credible evidence shows that the relevant product market is all oral potassium supplements that can be prescribed by a physician for a patient in need of a potassium supplement. F. 29-118.

a. Functional interchangeability of potassium supplements

The relevant market for purposes of antitrust litigation is the "area of effective competition" within which the defendant operates. *Tampa Elec.*, 365 U.S. at 327-28. As the Supreme Court explained in *E.I. du Pont Nemours*:

> The 'market' which one must study to determine when a producer has monopoly power will vary with the part of commerce under consideration. The tests are constant. The market is composed of products that have reasonable interchangeability for the purposes for which they are produced -- price, use and qualities considered.

351 U.S. at 404.

In defining a relevant product market, courts look to determine if products are "reasonably interchangeable." Courts consistently look to reasonable interchangeability as the primary indicator of a product market. *See 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. v. Ford Motor Co.*, 952 F.2d 715, 722, 726 (3d Cir. 1991) (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); *In re Liggett & Myers, Inc.*, 87 F.T.C. 1074, 1163 (1976) (premium and economy dog food found to be in the same market in view of interchangeability of use). *See also In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 297, 310-11 (E.D. Mich. 2001) ("The pharmaceutical market is fundamentally different from the market for other products. In the pharmaceutical industry, there is a government-assured complete interchangeability of drug products.").

The first step in determining interchangeability of potassium supplements is to determine who makes the selection regarding which potassium supplement to be used. Potassium supplements are given by doctors to hypertensive patients to treat or prevent hypokalemia, a lack of potassium caused by the use of diuretic medications. F. 38. The doctor is the most important link in the chain of those involved in the decision of which potassium supplement to prescribe. F. 38, 118. The doctor diagnoses that a potassium supplement is required for the patient. F. 38, 118. The doctor is the one who is knowledgeable about what products/drugs are available to meet the patient's needs. Professor Bresnahan acknowledged that the demand for potassium begins with a patient presenting himself/herself to a doctor and receiving a potassium supplement prescription. F. 38, 118.

There is insufficient evidence to show that the patient has any control over this decision. After the doctor makes the diagnosis and writes the prescription, the pharmacy fills that prescription. F. 39, 118. The patient and/or medical insurance pay for the prescription. The credible evidence demonstrates that the pharmacist has little or no control over which potassium supplement product to dispense. In many states, the law allows no change. In some states, a generic may be substituted. F. 22-23. Thus, between the doctor, the pharmacist, and the patient, it is the doctor who exercises most, if not all, control over which potassium supplement product is selected for any given patient. Accordingly, the only logical place from which to determine the relevant product market is from the array of therapeutically substitutable choices available to the doctor.

In 1997, more than 25 firms sold potassium supplements, including Schering-Plough and Upsher-Smith. F. 31-37. All forms of potassium are considered to be therapeutically equivalent; they all deliver potassium. F. 43-48. The high degree of interchangeability between various potassium products, including 20 mEq sustained-release products, was confirmed by Complaint Counsel's fact witnesses, Dean Goldberg and Russell Teagarden. F. 49-55.

Dean Goldberg of United HealthCare ("UHC") testified that there is a substantial "degree of choice" in the potassium chloride market. F. 50. Goldberg further testified that most, if not all, potassium chloride products are therapeutically equivalent. F. 50. Goldberg also confirmed that reasonable substitutes exist to the 20 mEq sustained release potassium chloride product and, that physicians consistently prescribe those products. F. 50.

Russell Teagarden, a licensed pharmacist, of Merck-Medco, the nation's largest Physician Benefits Manager ("PBM"), testified that there is no separate listing for 20 mEq potassium chloride products on its formulary. F. 51-54. 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. F. 51-54. He also testified that at many times, for example in 1993, 1994, and 1995-96, Merck-Medco did not even list K-Dur 20 as a prescription drug on its formulary. F. 51-54. Instead, Merck-Medco's formularies at those times simply listed other potassium supplements sold by other pharmaceutical companies. F. 51.

In addition, Professor 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. F. 87.

The evidence demonstrates that many types of potassium supplements are interchangeable with K-Dur 20. Accordingly, because there are many other acceptable potassium supplements which may be substituted, the relevant market is not limited to 20 mEq potassium supplements.

b. Pricing of potassium supplements

Complaint Counsel has taken the position that the proper inquiry to determine the relevant market is not whether the products are functionally interchangeable, but whether the products constrained each other's prices. CCPTB at 85-86. Complaint Counsel relies on *In re Coca-Cola Bottling Co. of the Southwest*, which held that the relevant inquiry in conducting an antitrust analysis is not whether "certain [products] competed against each other in a broad sense," but instead whether such "products were sufficiently substitutable that they could constrain" each other's pricing. 118 F.T.C. 452, 541-42 (1994). *Coca-Cola Bottling* was a merger case with an overriding focus on the combined power to influence the market which would be wielded by the proposed merger partners. In addition, as stated below, *Coca-Cola Bottling* cited *Brown Shoe* with approval. *Id.*

The Commission has not limited the inquiry to whether certain products are sufficiently substitutable that they could constrain each others products. *E.g.*, *Int'l Assoc. of Conference Interpreters*, 123 F.T.C. 465, 640 (1997) (Section 2 case) (the Commission generally examines what products are reasonable substitutes for one another through a consideration of price, use and qualities). Moreover, in the context of prescription of drugs, the Commission in, *In re Warner Lambert Co.*, 87

F.T.C. 812, 877 (1976), found that branded and unbranded thyroid products constituted a single product market despite "lack of price elasticity."

Complaint Counsel cites to numerous cases for the assertion that a price difference can lead to a finding of a separate product market. CCPTB at 85 and 86 n.33. But these cases utilize the Supreme Court's *Brown Shoe* analysis and virtually always consider other *Brown Shoe* factors such as special characteristics, industry recognition, distinct customers, and other *Brown Shoe* "practical indicia." *See FTC v. Staples*, 970 F. Supp. 1066, 1075-80 (D.D.C. 1997) (extensive reliance on *Brown Shoe* "practical indicia" for product market, including special characteristics of office superstores, industry recognition, extensive evidence of cross-elasticity of demand); *FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 45 (D.D.C. 1998) (relies on *Brown Shoe*, in particular unique features of the drug wholesaling industry, including specialized customers such as hospitals dependent on wholesalers, to find a distinct product market; merger case); *Coca-Cola*, 118 F.T.C. at 541-42 (citing *Brown Shoe* with approval and conducting extensive review of sales channel differences between home market and cold drink market); *In re Olin Corp.*, 113 F.T.C. 400, 603 (1990) (liquid chlorine pool bleach in separate market from dry pool sanitizer where "physical and technical characteristics" differed; chemical concentration of active ingredient, chlorine, differed; shelf life differed; and customers were geographically distinct and functionally distinct – pool service companies vs. homeowners).

The pharmaceutical industry case Complaint Counsel cites, *Smith-Kline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1978), found cephalosporin antibiotics to be a distinct product market from other antibiotics not because of price difference, but because, applying *Brown Shoe*, the Third Circuit found cephalosporins had special characteristics. Cephalosporins were (a) broad spectrum antibiotics "effective against a wider range of infectious organisms than are other antibiotics;" *id.* at 1064; ("cephalosporins are effective against the organism Klebsiella" staphylococci and gram negative bacilli, as contrasted with penicillins that "tend to be active against one but not the other"); (b) used for specialized patients: "cephalosporins are generally used in treating penicillin-allergic patients," *id*. at 1064; and (c) were "less toxic" than some other anti-infectives. *Id.* These "sufficiently unique features" are not present here where K-Dur 20 and other potassium chloride products contain precisely the same therapeutic agent and are "therapeutically equivalent."

c. Complaint Counsel did not prove a single brand market

Although Complaint Counsel claims it does not have to prove relevant market, Complaint Counsel alleges that Schering had market power and a monopoly in the market for 20 mEq potassium supplement. However, at all times relevant, Schering had a valid patent for the 20 mEq potassium supplement. Therefore any monopolization or market power existed by virtue of the '743 patent. *See Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 16 (1984) (When the government has granted the seller "a patent or similar monopoly over a product, it is fair to presume that the inability to buy the product elsewhere gives the seller market power.")

d. Complaint Counsel did not present pricing data to support an *Indiana Federation of Dentists* analysis

Complaint Counsel cites to *Indiana Fed'n of Dentists*, 476 U.S. at 460-61, to show that "proof of actual detrimental effects . . . can obviate" the need for an inquiry into market power. CCPTB at 83. However, as discussed *infra*, the pricing evidence offered by Complaint Counsel's expert is inadequate in many respects and does not support an *Indiana Federation* analysis.

Complaint Counsel's expert Professor Bresnahan did not study systematically Schering's pricing of K-Dur 20, Upsher-Smith's pricing for Klor Con 10 or Klor Con 8 potassium products and did not have or offer pricing data on other competitors. F. 419. Complaint Counsel's expert did not study the costs of Schering or other potassium supplement producers. F. 423. Complaint Counsel's expert did not study rebates, promotional allowances, or free goods, that affect the net pricing that Schering's customers received. F. 424.

Although Complaint Counsel sought to demonstrate that the price of K-Dur 20 rose, proof of one firm's prices rising, in a vacuum, cannot lead to any inference as to the relative price increase or decrease of Schering's K-Dur 20 product over time. An analysis under *Indiana Federation* requires that more be proven. *See Levine v. Central Florida Med. Affiliates*, 72 F.3d 1538, 1552 (11th Cir. 1996) (plaintiff's proof that defendant's prices (doctor's fees) had risen was legally insufficient because there was no proof of other doctors' fees or costs to compare those price increases with). Also, potassium purchasers had more than 20 firms to choose from to obtain therapeutically equivalent product, F. 31-37, clearly sufficient alternative choices to defeat an *Indiana Federation* claim. *See Flegel v. Christian Hosp., N.E.-N.W.*, 4 F.3d 682, 689 (8th Cir. 1993) (plaintiff provided insufficient evidence of detrimental effects under *Indiana Federation* where patients had the option of receiving care at other hospitals).

e. Complaint Counsel did not present a legally cognizable submarket under *Brown Shoe*

Brown Shoe v. United States, 370 U.S. 294, 325 (1962) introduced into merger law the concept of submarkets within the relevant market. *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 218 (D.C. Cir. 1986). The Supreme Court identified several "practical indicia" that may be used to delineate submarkets:

> The boundaries of such a submarket may be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors.

Brown Shoe, 370 U.S. at 325. "These indicia seem to be evidentiary proxies for direct proof of substitutability." *Rothery Storage*, 792 F.2d at 218; *H.J., Inc.*, 867 F.2d at 1540 ("[T]he same proof which establishes the existence of a relevant product market also shows (or in this case, fails to show) the existing of a product submarket.").

Complaint Counsel argues that a *Brown Shoe* analysis is not appropriate. Nevertheless, the Complaint specifically defined 20 milliequivalent extended-release potassium chloride tablets and capsules as a "narrower market" contained within the relevant market of all potassium chloride supplements approved by the FDA. Complaint at ¶ 21. Thus to determine whether "20 milliequivalent extended-release potassium chloride tablets and capsules" is a separate submarket, a *Brown Shoe* analysis follows.

1. "Industry Or Public Recognition" Of Distinct Markets

Complaint Counsel did not prove 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 fact witnesses from Merck-Medco and United HealthCare, two important industry participants, provided no testimony to prove that the industry recognizes 20 mEq sustained-release potassium chloride products as a separate and distinct market from the overall potassium chloride market. F. 49-55.

In applying this factor, courts look to industry publications, the classification of a class of products in a separate class, perceptions of customers and the firms' marketing documents. *See, e.g., Moore Corp. v. Wallace Computer Servs., Inc.*, 907 F. Supp. 1545, 1576 (D. Del. 1995) (citation omitted). These materials uniformly support a broad potassium supplement market; Professor Bresnahan admitted that he could not cite any pharmaceutical trade periodicals that treat K-Dur 20 as a product with unique features. F. 81. Data from IMS has a single category, 60110, for "Potassium Supplement Chloride" in which K-Dur 20 is but one of more than 30 products sold by more than 25 different firms tracked by IMS. F. 83.

Professor Bresnahan conceded that Schering's marketing documents for K-Dur 20 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. F. 60. Schering tracked the progress of its substantial investment in advertising and marketing by monitoring market share gains in terms of the overall potassium market. F. 60. 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. F. 60. The marketing documents of Schering's potassium rival, Upsher-Smith, demonstrate that one of the major competitors to the Upsher-Smith Klor Con product line, including the Klor Con 10 wax matrix, was K-Dur 20. F. 60 Upsher-Smith targeted K-Dur 20 in a series of advertisements urging doctors to substitute two Klor Con 10s for a 20. F. 64-69. Thus, the marketing perceptions of both companies were that K-Dur 20 competed in the broader potassium market. *See,*

e.g., Moore, 907 F. Supp. at 1576 ("neither company has historically considered [the product at issue] as a category unto itself;" finding broader product market under *Brown Shoe*).

2. "Product's Peculiar Characteristics And Uses"

As detailed in the preceding section, Complaint Counsel did not prove that K-Dur 20 has "peculiar characteristics and uses" than other potassium supplements. All potassium supplements have the same purpose: to deliver potassium to hypokalemic patients. F. 43-48.

3. "Unique Production Facilities"

Complaint Counsel 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 conceded at trial that the 10 and 20 mEq products are produced in the same plant. F. 85-86. With the same production facilities, the product facility factor cannot support a separate K-Dur 20 product market. *See, e.g., United States v. Consol. Foods Corp.*, 455 F. Supp. 108, 125 (E.D. Pa. 1978) (fresh and frozen institutional pies in same product market under *Brown Shoe* where "[m]anufacturing facilities for both products are virtually the same").

4. "Distinct Customers"

Complaint Counsel did not prove that K-Dur 20 is directed toward a distinct class of customers. In fact, Bresnahan testified that there is no distinct class of customers that prefer K-Dur 20. F. 87-88 (Bresnahan unaware of any group of potassium deficient patients that cannot by treated by Klor Con 10; Bresnahan "has seen nothing in those terms."). Similarly, Phillip Dritsas testified that there is no unique subgroup of patients that can only take K-Dur 20. F. 87-88.

5. "Distinct Prices"

Under this factor, for product lines to be considered separate, each potentially definable market must have distinct prices. *See U.S. Healthcare, Inc. v. Healthsources, Inc.*, 986 F.2d 589, 598-99 (1st Cir. 1993). Complaint Counsel failed to introduce sufficient 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 witness, Mr. Teagarden, conceded that K-Dur has the same relative price as other potassium chloride supplements. F. 89. Bresnahan conceded that branded potassium products had "comparable" prices to K-Dur 20. F. 89.

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. Bresnahan presented no statistical pricing study, and did not even have a pricing data set for K-

Dur 20, a price data set for K-Dur 10 or for Klor Con 10, and for its competitors in the sale of potassium supplements. F. 91, 419, 428.

Bresnahan concedes that a pricing difference alone does not suffice to prove a separate product market. F. 91 Nor did he study the demand for various forms of potassium to calculate demand elasticities. F. 422. Professor Bresnahan did not study the ratio of Schering's prices to costs, so he is unable to evaluate any rise in Schering's price for K-Dur 20 as related or unrelated to costs. F. 423.

6. "Sensitivity To Price Changes"

Complaint Counsel did not introduce sufficient evidence to demonstrate that there is price sensitivity between other potassium chloride supplements and K-Dur 20. Complaint Counsel's sole expert economist failed to conduct the analysis necessary to determine the degree of price sensitivity between 20 mEq sustained-release products and other potassium products. F. 112, 113, 419-23. Bresnahan had no pricing data sets for Schering, Upsher-Smith, Apothecon, or any other potassium competitor. F. 419. Lack of this evidence undermines Complaint Counsel's claims. *See, e.g., Lantec, Inc. v. Novell, Inc.*, 146 F. Supp. 2d 1140, 1148-49 (D. Utah 2001) (granting defendants' motion for judgment as a matter of law against Section 1 and 2 claims "[b]ecause there is no evidence on the costs of the various products or of how the consumer would react to a price increase in such costs, there is no evidence of price sensitivity" under *Brown Shoe* and thus plaintiffs' "evidence is insufficient to establish their definition of the relevant market").

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. The record evidence showed 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:

> 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.

F. 110; CX 20 (1998 K-Dur Marketing Plan, August 1, 1997, at SP 4040).

Similarly, the price sensitivity of the market to price reductions was dramatically demonstrated by the shift in sales to Apothecon, a new entrant in the sale of potassium supplements. F. 104-08. Price discounting was repeatedly noted in Upsher-Smith's potassium marketing documents. F. 104-08.

Furthermore, Bresnahan did not evaluate the brand advertising conducted by Schering. F. 424. Schering-Plough put millions of dollars into promoting the K-Dur brand and K-Dur 20 during the 1995-1997 time period. F. 411. Schering also invested heavily in free goods, rebates and other forms of discounting and marketing. 114-16. The magnitude of these expenditures demonstrates the price sensitivity of potassium supplement purchasers and the fact that Schering viewed itself as facing competition from various forms of potassium supplements prior to September 1, 2001. From October 1, 1997 to June 30, 2001, Schering spent $136 million in rebates it paid K-Dur customers. F. 115.

Schering outspent all of its potassium supplement competitors combined by more than a 4 to 1 margin on advertising and physician awareness activities. F. 411. This extensive advertising campaign was designed to compete against generic forms of potassium supplements. F. 411.

7. "Specialized Vendors"

The last *Brown Shoe* factor asks whether there are "specialized vendors" unique to K-Dur 20. No specialized vendors serve only 20 milliequivalent extended-release potassium chloride tablets and capsules. Patients who are hypokalemic receive prescriptions for a potassium supplement when they visit the doctor. F. 118. Prescriptions for extended-release potassium chloride supplements are dispensed at pharmacies. F. 118.

Complaint Counsel's witnesses did not establish by sufficient evidence any of these factors in order to prove that K-Dur 20 and its generic equivalents are a separate product market. Thus, an application of these "practical indicia" to the evidence presented at trial reveals that "K-Dur 20 and its generic equivalents" is not a separate product market.

E. First and Second Violations of the Complaint

The Complaint charges Respondents with four violations. The First and Second Violations of the Complaint charge that the agreements between Schering and its horizontal competitors, Upsher-Smith and AHP, unreasonably restrained commerce and therefore each agreement was an unfair method of competition.

1. The Legal Framework for Analysis of Horizontal Restraints

The FTC Act's prohibition of "unfair methods of competition" encompasses violations of other antitrust laws, including Section 1 of the Sherman Act, which prohibits agreements in restraint of trade. *California Dental Ass'n*, 526 U.S. at 763 n.3. The Commission relies on Sherman Act law in adjudicating cases alleging unfair competition. *E.g.*, *Indiana Fed'n. Dentists*, 476 U.S. at 451-52 (Commission based its ruling that the challenged policy amounted to a conspiracy in restraint of trade that was unreasonable and hence unlawful under the standards for judging such restraint developed in

the Supreme Court's precedents interpreting § 1 of the Sherman Act); *In re California Dental Assn.*, 121 F.T.C. 190, 292 n.5 (1996); *In re American Med. Assoc.*, 94 F.T.C. 701, 994 (1979).

Restraints on trade have been held unlawful under Section 1 of the Sherman Act, either when they fall within the class of restraints that have been held to be unreasonable per se, or when they are found to be unreasonable after a case-specific application of the rule of reason. In some circumstances, an abbreviated, or "quick look" rule of reason analysis may be appropriate. *California Dental*, 526 U.S. at 770. Complaint Counsel asserts that the challenged agreements are unreasonable restraints of trade under either the per se or rule of reason analysis. Although Complaint Counsel does not specifically urge "quick look" treatment, because many of the arguments Complaint Counsel advances relate to an abbreviated rule of reason approach, this method of analyzing the agreements is also addressed. Regardless of the method of analysis employed, the essential inquiry remains the same -- whether or not the challenged restraint enhances or impairs competition. *National Collegiate Athletic Assn. v. Bd. of Regents*, 468 U.S. 85, 104 (1984) (*"NCAA"*).

2. The Per Se Approach Is Not Applicable

"[M]ost antitrust claims are analyzed under a 'rule of reason' . . . ." *State Oil Co. v. Kahn*, 522 U.S. 3, 10 (1997) (citations omitted); *Standard Oil*, 221 U.S. 1, 62 (1911); *Chicago Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918) (courts generally determine the reasonableness of a particular agreement by reference to the surrounding facts and circumstances under the rule of reason). Courts are free to depart from this analysis, and adopt per se rules, only in limited circumstances, after they have had sufficient experience with a particular type of restraint to know that it is manifestly anticompetitive. *Broadcast Music, Inc. v. Columbia Broad. Sys., Inc*., 441 U.S. 1, 9 (1979); *Continental T.V. Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 50 (1977) (the per se rule should only apply to conduct that has a "pernicious effect on competition" and "lack[s] . . . any redeeming virtue"). Examples of such practices are horizontal price fixing, *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150 (1940), *FTC v. Sup. Ct. Trial Lawyers Ass'n*, 493 U.S. 411 (1990); agreements to reduce output, *NCAA*, 468 U.S. at 99; territorial divisions among competitors, *United States v. Topco Assoc., Inc.*, 405 U.S. 596, 608 (1972); and certain group boycotts. *Northwest Wholesale Stationers v. Pac. Stationery & Printing Co.*, 472 U.S. 284, 289-90 (1985). "[C]ertain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal *per se* without inquiry into the harm it has actually caused." *Copperweld Corp. v. Independence Tube Corp*., 467 U.S. 752, 768 (1984). *See also Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990); *Topco Assoc., Inc.*, 405 U.S. 596, 608 (1972).

To fit its allegations into the per se category, Complaint Counsel advances two theories. First, Complaint Counsel characterizes the agreements as "temporal market allocations," dividing the time remaining on Schering's patent. Second, Complaint Counsel asserts that the agreements reduced output and increased prices by keeping Upsher-Smith's and AHP's cheaper generic versions of K-Dur 20 off the market until September 2001 and January 2004, respectively. However, the settlement

agreements fit neither of these molds. Further, because an agreement to settle patent litigation must be examined in the context in which the agreement arose, the per se approach is not appropriate.

a. Complaint Counsel has not presented a per se market division case

Complaint Counsel asserts, "[e]ach agreement is in economic substance a temporal market allocation arrangement, in which sales of K-Dur 20 are reserved to Schering for several years, while Upsher-Smith and AHP are required to refrain from selling their generic versions of K-Dur 20 during that time period. As such, each constitutes a horizontal market allocation agreement, a classic *per se* violation." CCPTB at 65. However, this case does not present a straightforward market division case. Rather, the claims, as framed by Complaint Counsel, raise two novel issues. First, whether a patent holder and a challenger to that patent can settle patent litigation with an agreement that divides the time remaining on the patent. Second, whether a patent holder can make a "reverse payment" to settle a patent dispute.

The classic per se violation cases involve territorial or geographic divisions of markets. *Palmer*, 498 U.S. at 49-50 (competitors agreed not to enter each other's territories and to share profits from sales in one of those territories); *Topco Assoc.*, 405 U.S. at 607-08 ("One of the classic examples of a violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition"). With the exception of the *Cardizem* and *Terazosin* cases, Complaint Counsel has cited no case that holds that a "temporal market allocation" is a per se violation and no case that prohibits a patent holder from allocating the time remaining under its patent by retaining the exclusive rights guaranteed by the patent for a number of years and then granting licences under the patent to allow manufacturers of generic versions to compete for the remaining time. *See In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682 (E.D. Mich. 2000); *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340 (S.D. Fla. 2000). *See also Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 811 (D.C. Cir. 2001).

The *Cardizem* and *Terazosin* cases can be distinguished on numerous grounds. The critical difference, though, is that those agreements did not involve final settlements of patent litigation; and they did not involve agreements permitting the generic company to market its product before patent expiration. In *Terazosin*, the court found: "Abbott's confidential agreement with Geneva did not resolve its action before the Northern District of Illinois; in fact, it tended to prolong that dispute to Abbott's advantage." 164 F. Supp. 2d at 1350. Likewise, in *Cardizem*, the challenged agreement "did not resolve the pending patent claims; . . . Rather than facilitating or fostering an expeditious resolution of the HMRI/Andrx patent infringement suit, . . . [the agreement and payments] created the incentive to pursue the litigation beyond the district court and through the appellate courts." 105 F. Supp. 2d at 705.

In addition, Complaint Counsel's challenge to what Complaint Counsel has characterized as "reverse payments" is far from an "established" antitrust violation. The novelty of challenges to "reverse payment" patent infringement settlements was acknowledged by Complaint Counsel's expert witnesses at trial. Professor Bresnahan testified that there was no economic literature on the topic of reverse payments prior to the filing of suit in this case. Bresnahan, Tr. 644-45. Professor Bazerman testified that he had never heard of the phrase "reverse payments" prior to his work in this case. Bazerman, Tr. 8569. Applying a per se rule to a practice that is so new would be inappropriate. *Broadcast Music, Inc.*, 441 U.S. at 9; *Arizona v. Maricopa County Med. Soc'y*, 457 U.S. 332, 344 (1982).

Courts have been reluctant to create new per se rules. *Indiana Fed'n of Dentists*, 476 U.S. 447, 458-59 (1986) ("We have been slow . . . to extend *per se* analysis to restraints imposed in the context of business relationships where the economic impact of certain practices is not immediately obvious."); *Broadcast Music, Inc.*, 441 U.S. at 9 ("[I]t is only after considerable experience with certain business relationships that courts classify them as *per se* violations.") *See also Maricopa County*, 457 U.S. 332, 344 (1982) ("Once experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it, it has applied a conclusive presumption that the restraint is unreasonable.").

The few decisions by U.S. district courts adjudicating claims arising from the agreements entered into between Hoechst Marion Roussell and Andrx and between Abbott and Zenith and Geneva hardly constitute "considerable" experience. Further, the factual differences between the challenged agreements in *Cardizem* and *Terazosin* and the challenged agreements here distinguish those cases from the instant one. Without established case law holding that temporal market allocations pursuant to a patent or payments in connection with the settlement of patent litigation are per se violations, the "considerable experience" needed to support per se condemnation is lacking and application of the per se rule is inappropriate.

b. Complaint Counsel has not presented a per se case of reduced output and increased prices

Complaint Counsel alleges "that the challenged payments to stay off the market directly limit competition on price and output and are inherently likely to delay the entry of lower-priced alternatives and to enable Schering to maintain high prices without fear of losing market share." CCPTB at 65. This case, however, does not present a straightforward case of an agreement to reduce output or set prices.

The agreements, on their face, set no limits on output or prices and Complaint Counsel does not argue that Schering dictated the price at which Upsher-Smith and ESI may sell their products or the quantities they may sell upon entry. The agreements do, however, establish that Upsher-Smith and ESI may not enter the market with their generic versions of K-Dur 20 until September 2001 and January 2004, respectively. Complaint Counsel makes the argument that, by setting these entry dates,

Respondents, in effect, limited the output – by eliminating Upsher-Smith's and ESI's output – that would have been available for the periods of up until September 2001 and January 2004. Complaint Counsel further argues that, because Schering was unrestrained from competition from the generics, the agreements enabled Schering to increase prices by charging supra competitive prices for K-Dur 20.

Complaint Counsel's argument ignores the critical fact that these agreements are agreements to settle patent litigation. There is no evidence that the '743 patent is invalid. F. 124. There is no evidence that Schering's initiation of the patent infringement suits against Upsher-Smith and ESI was not for purposes of defending the '743 patent. F. 128, 331. Indeed, Hatch-Waxman encourages patent holders to initiate patent litigation to defend their patents by requiring ANDA applicants to notify patent holders of Paragraph IV Certifications and imposing a 45 day framework for patent holders to initiate patent infringement suits against generic manufacturers. 21 U.S.C. § 355(j); *Mylan*, 139 F. Supp. 2d at 9. Unless determined to be invalid, the '743 patent gives Schering the right to limit output - by excluding manufacturers of infringing drugs from the market until September 2006. *See* 35 U.S.C. § § 101, 271, 281. *Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 135 (1969) ("The heart of his legal monopoly is the right to . . . prevent others from utilizing his discovery without his consent."). And, this patent gives Schering the right to charge monopolistic prices for its patented product. "Such an exclusion of competitors and charging of supracompetitive prices are at the core of the patentee's rights, and are legitimate rewards of the patent monopoly." *United States v. Studiengesellschaft Kohle, M.B.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981).

It is not immediately obvious whether output was reduced and prices were increased by operation of Schering's legal, patented monopoly or by operation of the agreements entered into between Schering and Upsher-Smith and Schering and ESI. Further, because it is not immediately obvious that Upsher-Smith or ESI could have entered the market sooner than the agreed upon dates, it is not immediately obvious that output was reduced. "[T]he Supreme Court has made it clear that the *per se* rule is a 'demanding' standard that should be applied only in clear cut cases." *Law v. NCAA*, 134 F.3d 1010, 1019 (10th Cir. 1998) (*citing Continental T.V.,* 433 U.S. at 50). Because this case does not present a clear cut case of restraints where the economic impact is "immediately obvious" (*Indiana Fed'n of Dentists*, 476 U.S. at 459), per se treatment is not appropriate and a full rule of reason analysis is required.

c. The agreements challenged by Complaint Counsel are not in the class of agreements with no redeeming virtues

Settlements of intellectual property lawsuits are not in a class of per se agreements that, in the words of the Supreme Court in *White Motor Co. v. United States*, 372 U.S. 253 (1963) "lack … any redeeming virtue." *Id.* at 263. All settlements have redeeming virtue, providing important procompetitive benefits that must be taken into consideration in any antitrust analysis. *See, e.g., Speed Shore Corp. v. Denda*, 605 F.2d 469, 473 (9th Cir. 1979) (court must balance "deeply-instilled policy of settlement[s]" against claim that patent settlement unreasonably restrained trade); *Aro*

Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976) ("Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming. . . . By such agreements are the burdens of trial spared to the parties, to other litigants waiting their turn before over-burdened courts, and to the citizens whose taxes who support the latter. An amicable compromise provides the more speedy and reasonable remedy for the dispute."). For example, one of Schering's expert witnesses, Robert Mnookin, testified that society benefits when settlements allow the parties to conserve resources and avoid transaction costs, which may include not only legal fees, but also the time and distraction of the parties and their personnel. F. 384. Mr. Mnookin also testified that settlements can mitigate uncertainty and allow the parties to avoid the risks of litigation, thus creating economic efficiencies. F. 384. This is especially true of settlements of patent infringement cases, like the Upsher-Smith and ESI settlements. *See Grunin v. Int'l House of Pancakes*, 53 F.2d 114, 123 (8th Cir.), *cert. denied*, 423 U.S. 864 (1975) ("The very purpose of compromise is to avoid the delay and expense of such a trial."); *Boston Scientific Corp. v. Schneider (Europe) AG*, 983 F. Supp. 245, 270-71 (D. Mass. 1997) (upheld settlement agreement as not anticompetitive based on the "general rule that settlements and cross-licensing agreements do not, without something more, violate the antitrust laws."). Under the Upsher-Smith settlement agreement, for example, consumers are enjoying low priced generic versions of K-Dur 20 today. In the absence of the settlement, it is impossible for anyone to say whether there would be generic competition today or not because we can't know who would have won the litigation. *See* Bresnahan, Tr. 8230.

Although the Supreme Court has utilized the per se approach in cases involving settlements of patent disputes, in each of those cases, the patent holder engaged in conduct that reached beyond the rights conferred by the patent and engaged in conduct that was in violation of antitrust law. *E.g.*, *United States v. Masonite Corp.*, 316 U.S. 265, 282-83 (1942) (finding licensing agreement where patent holder set prices a violation of Sherman Act); *United States v. Singer Mfr. Co.*, 374 U.S. 174, 197 (1963) (finding patent interference settlement unlawful where the dominant purpose of a settlement was not to settle priority, but to exclude a mutual competitor of the parties); *U.S. v. New Wrinkle Inc.*, 342 U.S. 371, 380 (1952) (finding a licensing agreement between patent owner and manufacturer which served as means for owner to set prices a per se violation of Sherman Act); *U.S. v. Line Material Co.*, 333 U.S. 287, 314-15 (1948) (finding agreements to cross license patents which fixed the price of the patented device a per se violation). As analyzed below, the conduct engaged in by Schering was not proven to be beyond the rights conferred by the patent. Accordingly, these cases do not command the application of the per se rule.

d. The effects of the agreements cannot be presumed

Complaint Counsel argues that the anticompetitive effects of these agreements are so clear that the restraints should be deemed per se unreasonable. CCPTB at 46, 65. *Northern Pacific Ry. v. United States*, 356 U.S. 1, 5 (1958) ("[T]here are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable."). It is inappropriate in this case, however, to presume effects, for to do so would

require a presumption that the '743 patent was either invalid or not infringed by Upsher-Smith's and ESI's products. As discussed in Section E.4.b. *infra.*, to make this presumption would be contrary to law and the substantial, reliable evidence presented at trial. Accordingly, effects will not be presumed and the agreements will be analyzed under the rule of reason approach.

3. The Quick Look Approach Is Not Applicable

An abbreviated or "quick look" analysis under the rule of reason may be utilized when "the great likelihood of anticompetitive effects can easily be ascertained." *California Dental Ass'n*, 526 U.S. at 770. Quick look analysis may be appropriate to analyze agreements to restrict output. *NCAA*, 468 U.S. at 110 ("naked restraint on price and output requires some competitive justification even in the absence of a detailed market analysis"). However, where the "anticompetitive effects of given restraints are far from intuitively obvious, the rule of reason demands a more thorough enquiry into the consequences of those restraints" than can be performed using an abbreviated rule of reason analysis. *California Dental Ass'n*, 526 U.S. at 759.

The case presented by Complaint Counsel fails to present a situation in which the likelihood of anticompetitive effects is obvious. It is possible that Upsher-Smith and ESI might have entered the market prior to September 2001 and January 2004, respectively. However, it is also of course possible that they might not have entered the market until September 2006, upon the expiration of Schering's patent, or not at all. Faced with a set of different conflicting possibilities, the Supreme Court in *California Dental Ass'n*, held "that the plausibility of competing claims about the effects of the professional advertising restrictions rules out the indulgently abbreviated review to which the Commission's order was treated. The obvious anticompetitive effect that triggers abbreviated analysis has not been shown." 526 U.S. at 778.

Here, Complaint Counsel has presented one plausible explanation for Schering's payments of $60 million to Upsher-Smith and of $15 million to ESI – that these were payments to delay the generics' entry in the market. But, as analyzed *infra*, this explanation is based largely on the opinion testimony of Complaint Counsel's economic expert that manufacturers of brand name drugs have economic incentives to keep generic manufacturers off the market in order to retain monopoly profits. This explanation is also based on the opinion testimony of Complaint Counsel's valuation expert who testified that Schering's payment to Upsher-Smith was grossly excessive. Respondents also offer plausible explanations, supported by evidence, - that the payments were made to settle legitimate patent disputes and for separate pharmaceutical products at fair value. Given the plausibility of competing claims about whether the payments were only for delay, the obvious anticompetitive effect "that triggers abbreviated analysis has not been shown" (*California Dental Ass'n*, 526 U.S. at 778) in this case.

4. Under the Rule of Reason, Complaint Counsel Has Not Demonstrated That These Agreements Are Illegal

a. Complaint Counsel must prove effect on competition

In a rule of reason case, Complaint Counsel must prove that the challenged agreements had the effect of injuring competition. "The Supreme Court has made clear that the rule of reason contemplates a flexible enquiry, examining a challenged restraint in the detail necessary to understand its competitive effect." *In re California Dental Assoc.*, 121 F.T.C. at 308 (*citing NCAA*, 468 U.S. at 103-110) "An analysis of the reasonableness of particular restraints 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." *Topco Assoc.*, 405 U.S. at 607. *See also Todd v. Exxon Corp.*, 275 F.3d 191, 214 (2d Cir. 2001) (plaintiff must present evidence to support allegation that challenged conduct had anticompetitive effect); *All Care Nursing Service, Inc. v. High Tech Staffing Servs., Inc.*, 135 F.3d 740, 749 (11th Cir. 1998) ("To satisfy the rule of reason, the plaintiff must prove that the [conduct] had an adverse effect on competition.").

The fact that a case proceeds under Section 5 of the FTC Act does not alter the requirement that anti-competitive effects must be proved with evidence. *See California Dental Assoc. v. FTC*, 224 F.3d 942, 958-59 (9th Cir. 2000) (FTC's failure to demonstrate substantial evidence of a net anticompetitive effect resulted in remand with direction that the FTC dismiss its case). *See also Boise Cascade Corp. v. FTC*, 637 F.2d 573, 582 (9th Cir. 1980) (absence of evidence reflecting an anticompetitive effect rendered Commission order unenforceable); *see also E.I. duPont de Nemours & Co. v. FTC*, 729 F.2d 128, 141 (2d Cir. 1984) (challenged practice can only be found to be unfair method of competition under § 5 if weight of evidence shows competition substantially lessened and clear nexus between challenged conduct and adverse effects); *see also Interpreters*, 123 F.T.C. at 640 (Complaint Counsel failed to demonstrate anticompetitive effects of certain association rules).

The cases relied upon by Complaint Counsel, *Summit Health, Ltd. v. Pinhas*, 500 U.S. 322, 330 (1991) and *Goldfarb v. Virginia State Bar*, 421 U.S. 773, 785 (1975), do not support Complaint Counsel's proposition that Complaint Counsel need not prove or quantify actual effects to support a claim under Section 5. *Summit Health* holds that a defendant need not prove an actual effect on interstate commerce in order to establish federal jurisdiction. 500 U.S. at 330 ("'If establishing jurisdiction required a showing that the unlawful conduct itself had an effect on interstate commerce, jurisdiction would be defeated by a demonstration that the alleged restraint failed to have its intended anticompetitive effect. This is not the rule of our cases.'") (citation omitted). *Goldfarb* holds that in order to establish that a challenged activity affects interstate commerce, plaintiff need not quantify the expected effect. 421 U.S. at 785. "[O]nce an effect is shown, no specific magnitude need be proved." *Id.* Thus, Complaint Counsel is not relieved of showing effects simply because this case was brought under Section 5 of the FTC Act, and not under Section 1 of the Sherman Act.

b. Complaint Counsel has not proven that the agreements delayed competition

Complaint Counsel alleges that the agreements between Schering and Upsher-Smith and between Schering and ESI harmed competition because the agreements had the effect of delaying the introduction of Upsher-Smith's Klor Con M20 and ESI's Micro-K20 to the market. It is undisputed that the '743 patent gave Schering the lawful right to exclude infringing products from the market until September 5, 2006. It is undisputed that under the June 17, 1997 Agreement, Upsher-Smith gained a license under the '743 patent to sell a 20 mEq microencapsulated form of potassium chloride more than five years earlier than the expiration of the'743 patent. F. 156. It is undisputed that under the handwritten settlement agreement and final settlement agreement between Schering and ESI, ESI gained a license under the '743 patent to sell a 20 mEq microencapsulated form of potassium chloride more than two and a half years earlier than the expiration of the '743 patent. F. 367, 372. And, it is undisputed that under license Upsher-Smith began selling Klor Con M20 on September 1, 2001. F. 94.

What is disputed is whether Upsher-Smith and ESI could have entered the market any earlier than September 1, 2001 and January 1, 2004, respectively. If Upsher-Smith and ESI could have legally entered the market prior to September 2001 and January 2004, but were paid only for delay and not as part of a legitimate settlement, as Complaint Counsel alleges, then the challenged agreements would have anticompetitive effects. Thus, to prove anticompetitive effects, Complaint Counsel must prove that better settlement agreements or litigation results would have resulted in Upsher-Smith and ESI selling their generic equivalents prior to September 1, 2001 and January 1, 2004. Complaint Counsel did not demonstrate this. Nor has Complaint Counsel brought forth evidence that the entry dates agreed upon were "unreasonable." Thus, without sufficient evidence to prove that Upsher-Smith or ESI would have entered the market sooner than the agreements allow, Complaint Counsel failed to prove that any unlawful delay resulted from the agreements.

(i) The '743 patent operates to exclude all non-infringing products until September 5, 2006

"A patent shall be presumed valid." 35 U.S.C. § 282. This is long established law that cannot be ignored. *E.g., Doddridge v. Thompson*, 22 U.S. 469, 483 (1824) (a patent is presumed to be valid, until the contrary is shown); *Cordis Corp. v. Medtronic, Inc.* 780 F.2d 991, 995 (Fed. Cir. 1995) (patents are presumed to be valid; until invalidity is proven, the patentee should ordinarily be permitted to enjoy the fruits of his invention). *But see Cardizem*, 105 F. Supp. 2d at 700 (characterizing defendants' arguments as based on "erroneous presumptions" by Andrx regarding whether a generic drug would infringe the patent). However, *Cardizem* cites no authority to support this apparent presumption of the pending patent case and to the extent it is a presumption of invalidity or non-infringement, it is contrary to well settled precedent. A presumption of infringement or invalidity of a patent is tantamount to grafting a section onto the Hatch-Waxman Act which is clearly not there. The making of the laws is a function of our Congress.

Under its '743 patent, Schering had the legal right to exclude Upsher-Smith from the market until Upsher-Smith either proved that the '743 patent was invalid or that its product, Klor Con M20, did not infringe Schering's patent. Similarly, Schering had the legal right under its '743 patent to exclude ESI from the market until ESI either proved that the '743 patent was invalid, or that its product, Micro-K20, did not infringe Schering's patent. *Doddridge*, 22 U.S. at 483; *Cordis*, 780 F.2d at 995. Application of antitrust law to markets affected by exclusionary statutes such as the Patent Act cannot ignore the rights of the patent holder. *In re Independent Service Organizations Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000) (court must give "due consideration to the exclusivity that inheres in the patent grant"); *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999) ("[S]ome measure must guaranteed that the jury account for the procompetitive effects and statutory rights extended by the intellectual property laws."); *Bement v. National Harrow Co.*, 186 U.S. 70, 88 (1902).

While Complaint Counsel acknowledges that the '743 patent gives Schering the right to exclude all infringing products, Complaint Counsel argues that antitrust laws prohibit Schering from paying Upsher-Smith and ESI to stay off the market. However, Complaint Counsel has not established that Schering paid Upsher-Smith and ESI to stay off the market because Complaint Counsel has not proved that Upsher-Smith or ESI could have even been on the market prior to the expiration of the '743 patent.

Indeed, Complaint Counsel acknowledges that it cannot prove that Upsher-Smith and ESI could have been on the market prior to September 5, 2006. In its post trial brief, Complaint Counsel states that it is impossible to reliably determine whether the Upsher-Smith and ESI products did not infringe Schering's patent or whether the alleged infringers would have prevailed in the infringement suits. CCPTB at 67-76. The evidence presented at trial confirms that the likely outcome of the patent disputes cannot reliably be predicted. *Id.*; F. 394. And because the outcome of the patent disputes cannot be predicted, the date on which Upsher-Smith and ESI could have entered, but for the agreements, cannot be determined. Complaint Counsel argues:

> Respondents, in advocating a test for competitive harm that cannot be done reliably, urge a rule that would effectively immunize settlements involving payments not to compete. Given the undeniable incentives for branded drug manufacturers and potential generic entrants to reach patent settlements that involve payments for delayed entry, the threat of serious harm to consumers is too great, and the likelihood of deterring procompetitive agreements is too small, to justify the approach advocated by respondents.

CCPTB at 67-76

Complaint Counsel's argument may hold intellectual appeal. However, simply because, based upon the theories it advanced in this case, Complaint Counsel cannot prove whether Upsher-Smith and

ESI would have come on the market earlier than September 2001 and January 2004, but for the $60 million and $15 million payments, does not relieve Complaint Counsel of its burden of proof. In *Andrx Pharm.*, 256 F.3d 799, the court, on a motion to dismiss, held, "[o]ne can fairly infer . . . that but for the Agreement, Andrx would have entered the market." *Id*. at 809. The court noted that Hoechst's ten million dollar quarterly payments were presumably in return for something that Andrx would not otherwise do, that is, delay marketing of its generic. *Id.* at 813. But in this case, after a lengthy trial, there is substantial evidence to support Respondents' defense that the agreements were legitimate agreements to settle vigorously contested patent litigation, and, in the case of Upsher-Smith, that the payment from Schering to Upsher-Smith was for Niacor-SR and the other drugs licensed from Upsher-Smith to Schering; and, in the case of ESI, that the patent litigation would not have settled without a payment from Schering to ESI and the licensing of other drugs from ESI to Schering. In the face of this substantial evidence, to agree with Complaint Counsel would require an inference or presumption of what Complaint Counsel has not proved and would effectively shift the burden of proof to Respondents, contrary to law, as discussed *supra*.

Complaint Counsel, relying on *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001), argues that it is not required to prove what would have happened, "but for" the challenged conduct. In *Microsoft*, the court noted, "neither plaintiffs nor the court can confidently reconstruct a product's hypothetical technological development in a world absent the defendant's exclusionary conduct." *Id*. The challenge for Complaint Counsel here is much narrower. Complaint Counsel is not asked to reconstruct a hypothetical technological development, but to demonstrate that, absent Schering's payments to Upsher-Smith and ESI, Upsher-Smith and ESI would have come on the market earlier than the agreements allowed. Complaint Counsel has not done so.

Further, even though the government in *Microsoft* was not required to reconstruct a product's hypothetical development in a world absent the defendant's exclusionary conduct, the government was required to prove effects:

> First, to be condemned as exclusionary, a monopolist's act must have an 'anticompetitive *effect*.' . . . Second, the plaintiff, on whom the burden of proof of course rests, … must demonstrate that the monopolist's conduct indeed has the requisite anticompetitive *effect*.

Microsoft, 253 F.3d at 58-59 (emphasis added). Thus, *Microsoft* does not relieve Complaint Counsel of proving the payments delayed entry.

(ii) Upsher-Smith and ESI would not have come on the market until the resolution of the patent infringement suits

The Hatch-Waxman Act does not provide immunity for patent infringement damages and there is no substantial evidence to demonstrate that Upsher-Smith and ESI would have entered the market before resolution of the patent infringement suits. The court, in *Cardizem*, accepted the plaintiffs' allegations as true, as it must on a motion to dismiss, that Andrx's generic drug would have entered the U.S. market on or about July 9, 1998, the date on which Andrx received FDA approval, but for its agreement with Hoechst. *Cardizem*, 105 F. Supp. 2d at 649. However, FDA approval does not mean generic entry will occur while patent disputes are unresolved. Since FDA approval of an ANDA does not shield a generic manufacturer from liability. 35 U.S.C. § 284; *King Instruments Corp. v. Perego*, 65 F.3d 941, 948 (Fed. Cir. 1995). The prudent practice, then, is for generic manufacturers to await the conclusion of patent litigation before marketing a product and risking financial ruin.

In this case, Upsher-Smith and ESI each received final FDA approval to market their generic versions of Schering's K-Dur 20 by November 1998 and June 1999, respectively. At the conclusion of trial, there is no credible evidence of when, if ever, ESI would have otherwise entered the market and, there is credible evidence that Upsher-Smith would not have entered the market if it was still entangled in patent litigation, even at the end of the 30-month stay and upon FDA approval. F. 391-92. For Upsher-Smith to have launched Klor Con M20 while the Schering '743 patent challenge was unresolved would have been "foolhardy" and potentially could have had dire consequences. F. 391-92.

c. Complaint Counsel did not prove that the payments were not to settle the infringement cases and for drugs licensed to Schering

(i) Upsher-Smith

The claims against Schering and Upsher-Smith rest upon the allegation that the $60 million payment from Schering to Upsher-Smith was not a bona fide royalty payment under a license for Niacor SR and five other products. The Complaint alleges: "The $60 million payment from Schering to Upsher-Smith was unrelated to the value of the products Upsher-Smith licensed to Schering." Complaint ¶ 45. The Complaint alleges that the royalty payments were in fact payments to delay the introduction of Upsher-Smith's AB-rated generic to K-Dur 20. Complaint ¶ 64. Complaint Counsel have described the $60 million in royalty payments as a "veil," "disguise," "sham," and "cover." CCPTB at 2-3, 6, 8, 26, 34.

Prior to trial, Complaint Counsel acknowledged that its case would fail if it could not prove that Schering paid Upsher-Smith for delay. At a July 25, 2001 hearing, Complaint Counsel answered a question from the bench as follows:

> JUDGE: I guess I need to ask you one more question. Then are you saying the Government has to prove the payment was for delay in order to win this case?

MR. KADES: Absolutely. That's what we will prove at trial. . . .

7/25/01 Tr. at 34. In its Post Trial Brief, Complaint Counsel reaffirmed that the Complaint requires them to prove that the $60 million was for delay rather than for a bona fide product license: "This case does not challenge the settlement of patent disputes by an agreement on a date of entry, standing alone, or the payment of fair market value in connection with 'side deals' to such an agreement." CCPTB at 43. Complaint Counsel's expert witness economist, Professor Bresnahan, agreed that a side deal at fair value did not raise competitive concerns:

> Q: All right, sir. Now, similarly had Upsher-Smith and Schering-Plough entered into an agreement that contained a side deal at fair value, same negotiation, they negotiate entry date and then they have a side licensing deal, and it contains fair market value consideration being exchanged between the parties, that would not flunk the Bresnahan test. That would not be anticompetitive according to you. Is that correct?
>
> A: That's right.
>
> Q: All right. So you don't have a problem with side agreements, as such; you want to make sure there's no net positive value flowing to the generic firm. Is that correct?
>
> A: That's — that's my test, yes.

F. 172. Professor Bresnahan confirmed that the determination of fair value was a subjective standard measured at the time of the transaction: "if Schering-Plough had made a stand-alone determination that it was getting as much in return from those products as it was paying, then I would infer that they were not paying for delay." F. 172.

At trial, the evidence established that the June 17, 1997 Agreement between Schering and Upsher-Smith was a type of transaction that Complaint Counsel and their economist concede to be permissible: it was a settlement of a patent dispute by an agreement on a date of entry, with a side deal supported by fair value as determined at that time. The fact testimony at trial was unrebutted and credible in establishing that the licensing agreement was a bona fide arms-length transaction, and that Schering's royalty payments to Upsher-Smith were payments for the products being licensed to Schering, together with certain production rights. Contemporaneous documentary evidence, such as Mr. Audibert's commercial assessment and Schering's Board Presentation, corroborated that testimony. The opinion testimony of Complaint Counsel's expert witnesses, based largely upon theory, did not impeach that unrebutted and credible fact evidence. The substantial, reliable evidence refutes

Complaint Counsel's allegation that the $60 million paid to Upsher-Smith was "unrelated" to the products being licensed.

(A) The Evidence Establishes That The Niacor-SR License Was a Bona Fide Side Deal For Fair Value

Abundant evidence at trial established that the $60 million paid by Schering was fair value for Niacor-SR and the other licensed products. Upsher-Smith had for years invested heavily in Niacor-SR and in mid-1997 it appeared to be a highly promising product. F. 191-92. Start-up company Kos Pharmaceuticals had achieved a market capitalization of approximately $400 million almost entirely on the promise of its extended-release niacin product Niaspan, which, like Niacor-SR, had not yet obtained FDA approval for marketing. F. 152. Schering had a documented, pre-existing interest in an extended-release niacin product to enter the cholesterol-fighting market. F. 201-19. In the months preceding the licensing agreement with Upsher-Smith, Schering had engaged in extended negotiations with Kos over a possible U.S. co-promotion venture. F. 201-08. Schering had made a substantial written proposal to Kos, but Kos rejected it. F. 214-19. Shortly thereafter, the Niacor-SR opportunity arose. F. 138.

When the Upsher-Smith opportunity arose, Schering's James Audibert undertook a commercial assessment of Niacor-SR. F. 228. Mr. Audibert had extensive experience in the marketing of extended-release formulations, had considerable experience with cholesterol-reducing drugs, and had been involved in Schering's discussions with Kos relating to Niaspan. When he prepared his valuation of Niacor-SR, Mr. Audibert was not aware that the licensing opportunity had arisen in the context of a side deal to a patent settlement and was not aware of the amount of money that was being asked for the license rights by Upsher-Smith. F. 251. Mr. Audibert stated in his commercial assessment: "Niacor SR is expected to be launched in early 1999 with 3rd-year sales of $114 million." F. 251. "In summary, Niacor SR offers a $100+ million sales opportunity for Schering-Plough." F. 254.

The other pharmaceutical products that Upsher-Smith licensed to Schering, prevalite, Klor-Con 8, 10 and M20, and pentoxifylline, also had value. According to the presentation given to Schering's Board of Directors, Schering's staff forecasted sales "to be $8 million a year in the first full year of launch, growing to $12 million a year in the second full year, and then gradually declining in year four and thereafter." F. 165.

The June 17, 1997 agreement was contingent on approval by the Schering Board of Directors. F. 163. The presentation given to Schering's Board of Directors stated that, in the course of Schering's discussions with Upsher-Smith, Upsher-Smith indicated that a prerequisite of any deal would be to provide them with a guaranteed income stream to make up for the income that they had projected to earn from sales of Klor-Con, had they been successful in their suit. F. 163. The Board

was informed that Schering had made it clear to Upsher-Smith that any such deal would have to stand on its own merit, independent of the settlement. The Board presentation provided sales projections for Niacor-SR of $100 million plus in annual sales and showed a net present value of $225-265 million for the Niacor license. F. 164.

(B) Complaint Counsel did not meet its burden of proving that the Niacor-SR License was not a bona fide side deal for fair value

(i) Dr. Levy

To prove that the $60 million payment from Schering to Upsher-Smith was not a bona fide royalty payment under a license for Niacor SR and five other products, Complaint Counsel proffered Dr. Nelson L. Levy, an expert "in the field of pharmaceutical licensing and pharmaceutical valuation." F. 174. Dr. Levy testified that the $60 million payment made by Schering to Upsher-Smith cannot be considered to have been a license fee for Niacor-SR and the five generic products licensed. F. 315. Dr. Levy had three bases for this opinion. First, Levy concluded that the $60 million non-contingent fee was grossly excessive for Niacor-SR and the other licensed products, and greatly surpassed the non-contingent fees paid by Schering in other unrelated pharmaceutical transactions. F. 290, 296. Second, Levy bases his conclusion on his opinion that the due diligence conducted by Schering for Niacor-SR was strikingly superficial relative to industry standards on due diligence and Schering's own due diligence practices. F. 301-03. Third, Levy bases his conclusion on his opinion that after the settlement agreement was executed, neither Schering nor Upsher-Smith undertook behavior consistent with parties who had just entered into a licensing transaction, for which Schering committed to pay $60 million. F. 315-18.

Dr. Levy's testimony is contradicted by the greater weight of the evidence. Schering presented substantial, reliable evidence demonstrating that Niacor-SR and the other licensed products were valued at $60 million. F. 258-61. Schering presented substantial, reliable evidence demonstrating that Schering performed due diligence on Niacor-SR. F. 243-61. And, Respondents presented substantial, reliable evidence to explain Respondents' post deal conduct and attendant decisions not to pursue Niacor-SR. F. 262-74.

Furthermore, Dr. Levy's testimony is accorded less weight for three reasons. First, he performed no quantitative analysis of Niacor-SR or any of the other 5 products Schering received under the license agreement and did not consider the market value of Kos. F. 293. Second, Dr. Levy's opinions regarding value of Niacor-SR are founded in part on his conclusions regarding the safety and efficacy of Niacor-SR and his testimony demonstrated he lacked expertise in the area of cholesterol-lowering drugs and niacin. F. 308-14. Third, Dr. Levy's conclusion that the parties' post deal conduct is not behavior consistent with parties who had just entered into a licensing transaction for which Schering committed to pay $60 million is rebutted by the evidence Respondents presented on

their post deal conduct and discredited because Levy did not review many of the documents reflecting the parties' communications and continued work on the licensed products. F. 315-18.

(ii) Professor Bresnahan

Complaint Counsel also offered the expert testimony of Professor Bresnahan to prove Schering's payment was not for the Niacor license. Bresnahan did not attempt to value the rights Schering obtained under the licensing agreement and did not challenge the Niacor-SR sales projections, estimated cost of goods sold, net profit, or the economic value of $225-265 million presented to Schering's Board of Directors. F. 319. Instead, Bresnahan applied a "revealed preference" test and a "market test" and analyzed the parties' incentives to opine that the $60 million payment was not for the Niacor license. F. 320-26.

Under Bresnahan's "revealed preference" test, Bresnahan concluded that Schering's turning down of Kos' Niaspan "revealed" that Schering was not willing to make a large upfront payment for the comparable Niacor-SR product. F. 320. However, Schering demonstrated a genuine interest in Kos' sustained-release niacin product, projected substantial sales for that product, engaged in an extended dialogue with Kos, and made a serious offer incorporating a major financial commitment commensurate with the profit split under the contemplated co-promotion arrangement. F. 201-19. The substantial, reliable evidence demonstrates legitimate, credible reasons for Schering's preference of a licensing deal with Upsher-Smith over a co-marketing arrangement with Kos. F. 217-19.

Professor Bresnahan testified that because no other company had made Upsher-Smith an offer that included a substantial non-contingent payment for the licenses, Niacor-SR was not highly valued enough in the marketplace to justify a non-contingent payment, and therefore the $60 million non-contingent payment made by Schering to Upsher-Smith was not for Niacor-SR. However, in June 1997, Upsher-Smith was still in active discussions with a variety of companies to market Niacor-SR. F. 325, 196. Upsher-Smith executives believed that potential European licensees were showing "strong interest" in Niacor-SR and that a substantial up-front payment was warranted. Because Upsher-Smith terminated its marketing efforts after signing the exclusive agreement with Schering on June 17, 1997, no conclusions as to Niacor-SR's value can be drawn from this ongoing process. The substantial, reliable evidence presented by Schering demonstrates the factors Schering considered in valuing the Niacor-SR licence. F. 326. This evidence refutes the conclusion Bresnahan reached using his market test.

Professor Bresnahan also testified that Schering and Upsher-Smith had incentives to engage in a transaction trading a payment for delay and acted on those incentives. Ultimately, Professor Bresnahan was compelled to acknowledge that theoretical "incentives" hardly constitute evidence of actual improper conduct:

Q: Professor, is it your view that if a person has an economic incentive to violate the law, that leads to the conclusion that they did so?

A: No.

Bresnahan, Tr. 1105. These "incentives" are not legally dispositive. *See, e.g., Serfeez v. Jewel Food Stores*, 67 F.3d 591, 600 (7th Cir. 1995) (holding that "the presence of an economic motive is of very little probative value" and that "[t]he mere existence of mutual economic advantage, by itself, . . . supplies no basis for inferring a conspiracy"). Contrary to the theory offered by Bresnahan, the record testimony from all of the participants in the negotiations provides direct evidence that the parties did not exchange money for delay. F. 322-26.

The presentation made to Schering's Board of Directors when it approved the licensing agreement reported that Upsher-Smith had expressed a desire for "an income stream to replace the income that [it] had anticipated earning if it were able successfully to defend against Key's infringement claims." F. 163. As Professor Bresnahan acknowledged, (Bresnahan, Tr. 572-573), the presentation also reported: "we informed them that any such deal should stand on its own merit independent of the settlement." F. 163. The remainder of the presentation contained a detailed discussion and financial analysis justifying the licensing opportunity on its own merit. F. 163-66. Despite Professor Bresnahan's opinion otherwise, the Schering Board presentation confirms Schering's insistence that any licensing royalty payment to Upsher-Smith had to be independently supported by fair value.

(C) The terms of the June 17, 1997 agreement

Professor Bresnahan opined that Paragraph 11 of the June 17, 1997 agreement "links" Schering's royalty payments to the September 1, 2001 entry date. Bresnahan, Tr. 535-536. Paragraph 11 expressly describes the three payments totaling $60 million as "up-front royalty payment[s]." As evidenced by the negotiations leading up to June 17, 1997 agreement, Upsher-Smith and Schering each intended the term "royalty" to reflect that Schering would be paying for the licenses and associated production rights it was receiving from Upsher-Smith. This understanding of "royalty" comports with the common understanding of the term. *See, e.g., Sierra Club, Inc. v. C.I.R.*, 86 F.3d 1526, 1531 (9th Cir. 1996) (noting that "'royalty' commonly refers to a payment made to the owner of property for permitting another to use the property") (citing *Black's Law Dictionary* 1330-31 (6th ed. 1979)); *see also* Dennis W. Carlton and Jeffrey M. Perloff, *Modern Industrial Organization* 528 (3d ed. 2000) ("The patent holder may produce the product (or use its new process) or *license* (permit) others to produce it in exchange for a payment called a *royalty*.") (emphasis in original). Furthermore, in Paragraph 11, the designated payor of the "royalty" payments is "SP Licensee." "SP Licensee," which is first defined in Paragraph 7, is the recipient of Upsher-Smith's licenses in Paragraphs 7 through 10. F. 156, 161. The only natural and normal reading of Paragraph 11 is that "SP Licensee" is paying "royalties" for the licenses it is receiving in Paragraphs 7 through 10.

(ii) ESI

Complaint Counsel contends that the payment from Schering Plough to ESI was only made to delay generic entry by ESI. This is not a case of a naked payment to delay an entrant who is legally ready and able to compete with Schering because Schering's patent, as discussed *supra,* is presumed valid. Complaint Counsel introduced a dearth of evidence about the ESI settlement agreement in its case in chief. It introduced fact evidence only in the form of deposition testimony and investigational hearing transcripts of Schering and ESI personnel who negotiated the settlement, and a few documents relating to the settlement negotiations. Complaint Counsel offered opinion evidence in the form of about fifteen minutes of testimony about the ESI settlement by Professor Bresnahan. F. 378. Dr. Levy, Complaint Counsel's valuation expert, was not asked his opinion on the value of enalapril and buspirone. F. 380. Thus, no evidence of fair value was offered.

As discussed *supra*, Complaint Counsel has the burden of proof on all violations alleged in the Complaint. Respondent Schering had no duty or requirement to offer any evidence on the ESI agreement should Complaint Counsel not do so. Complaint Counsel did not present sufficient substantial, reliable evidence to support a conclusion that ESI could have or would have entered the market before the date set on the settlement agreement. Complaint Counsel also did not present sufficient substantial, reliable evidence to support a conclusion that the Schering-ESI patent litigation would have settled without the provision for the licensing agreement for enalapril and buspirone being part of that settlement or that any payment was not for fair value. Accordingly, there is no substantial, reliable evidence to conclude that the $15 million was paid only for unlawful delay.

Moreover, it is clear that parties to a patent dispute may exchange consideration to settle this litigation. The Supreme Court has rejected the argument that consideration renders an agreement unlawful. *See Standard Oil Co. v. United States*, 283 U.S. 163, 170-71 n.5 (1931) (noting that the interchange of rights and royalties in a settlement agreement "may promote rather than restrain competition").

d. Complaint Counsel has not demonstrated anticompetitive effects sufficient to shift the burden to Respondents to show procompetitive effects

Once a plaintiff has demonstrated that "great likelihood of anticompetitive effects" from agreements "can easily be ascertained," the burden shifts to a defendant to come forward with plausible procompetitive justifications. *California Dental Ass'n*, 526 U.S. at 770; *NCAA*, 468 U.S. at 113. Because Complaint Counsel has not demonstrated anticompetitive effects, analysis of Respondents' proffered justifications is not necessary.

5. Complaint Counsel Did Not Prove That The "Any Other Sustained Release Microencapsulated Potassium Chloride Tablet" Clause Restricted Competition

Complaint Counsel's position is that the Schering and Upsher-Smith settlement agreement contains additional collateral restraints which are anticompetitive. CCRB at 64. However, Complaint Counsel conceded that parties may settle patent litigation "by an agreement on a date of entry." CCPTB at 43. Any such settlement must necessarily identify the products that are the subject of the agreement – *i.e.* what the alleged infringer is permitted to market and what the alleged infringer is prohibited from marketing under the agreement. F. 168. This degree of specification is necessary in order to limit the alleged infringer's ability to go to market with another infringing product under the agreement. F. 168. It is not enough just to identify the subject of the agreement as "infringing products," as the parties involved in patent litigation necessarily disagree over what does or does not infringe the patent. F. 168. Such a specification would likely lead to renewed litigation, with its attendant costs and inefficiency. Thus, an "ancillary restraint" is ordinarily required to specify the products covered in the agreement by providing an objective description of what can and cannot be marketed prior to the agreed-upon entry date.

Ancillary restraints are permitted if, and precisely because, they are "reasonably necessary" to accomplish a contract's efficiency-enhancing purposes. *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"); *Rothery Storage*, 792 F.2d at 224 ("The ancillary restraint is subordinate and collateral in the sense that it serves to make the main transaction more effective in accomplishing its purpose.").

The efficiency-enhancing objectives of a patent settlement are clear. *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976) ("Public policy strongly favors settlement of disputes without litigation. Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming."). *See also Schlegal Mfg. Co. v. U.S.M. Corp.*, 525 F.2d 775, 783 (6th Cir. 1975) ("The importance of encouraging settlement of patent-infringement litigation . . . cannot be overstated.").

Under the Schering/Upsher-Smith settlement, the scope of products subject to the September 1, 2001 entry date agreement was as narrow as was "reasonably necessary" to accomplish the objectives of the settlement. Schering's '743 patent claims a "controlled release [microencapsulated] potassium chloride tablet . . . ." USX 713 at ESI EXH 000003. The Schering/Upsher-Smith settlement likewise covers any "sustained release microencapsulated potassium chloride tablet . . . ." F. 167. Upsher-Smith's witnesses verified that no other products in Upsher-Smith's pipeline were delayed by the ancillary restraint contained in paragraph 3, nor was such a result intended. F. 170.

Complaint Counsel's witness on this point, Bresnahan, testified that he had "no evidence" that anyone at Schering-Plough or Upsher-Smith had any product other than Klor Con M20 in mind at the time of the agreement. F. 171. With reference to paragraph 3, Bresnahan admitted that he had not examined Upsher-Smith's product pipeline between 1997 and 2001. F. 171.

Complaint Counsel's economist expert, Professor Bresnahan, expressly conceded that, assuming the settlement agreement is otherwise lawful, this provision expanding its coverage to a broader category of products is reasonable. F. 171. Accordingly, Complaint Counsel has failed to prove that the settlement agreement was broader than was "reasonably necessary" to settle the litigation.

6. Complaint Counsel Did Not Prove That the Schering/ Upsher-Smith Agreement Had the Effect of Blocking Other Potential Generic Competitors

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," (Complaint at. ¶ 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." Complaint at ¶ 62. Complaint Counsel failed to prove that any potential competitors were blocked or that the exclusivity period was manipulated or even discussed by Schering and Upsher-Smith.

The Complaint only alleges that one specific firm, Andrx, was blocked by Upsher-Smith's exclusivity. Complaint at ¶¶ 61-62. Lawrence Rosenthal, Executive Vice President of Sales and Marketing at Andrx, testified that **[redacted redacted redacted]** F. 395.

Executives at Upsher-Smith were not aware of any other potential competitors blocked from the market. F. 396. Professor Bresnahan testified that he is not aware of any potential competitors who were blocked from entering the alleged product market for K-Dur 20 as a result of the June 17, 1997 Agreement. F. 397.

The 180-day exclusivity period was never discussed between Schering and Upsher-Smith during their settlement negotiations. F. 399. 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. F. 399. Schering-Plough, similarly, acknowledges that the agreement did not make any reference to exclusivity and the subject was never even discussed. F. 399.

In the absence of proof that any other firm was blocked or that Schering and Upsher-Smith discussed the 180-day exclusivity period in their settlement negotiations, Complaint Counsel has failed

to prove that the June 1997 Settlement Agreement unlawfully delayed entry by other potential generic competitors.

F. Third and Fourth Violations of the Complaint

The Third and Fourth Violations of the Complaint allege that Schering has monopoly power in the manufacture and sale of potassium chloride supplements approved by the FDA and the narrower markets contained therein and engaged in conduct to unlawfully preserve such monopoly power and that Schering conspired separately with Upsher-Smith and ESI to monopolize the relevant markets. Complaint ¶ 70, 71. As detailed in Section D, *supra*, to establish monopolization or attempted monopolization, it is necessary to appraise the exclusionary power in terms of the relevant market for the product involved. *Spectrum Sports,* 506 U.S. at 455-56. The relevant market in this case is all oral potassium supplements that a physician can prescribe to a patient in need of a potassium supplement.

1. Complaint Counsel Did Not Prove That Schering Had Monopoly Power

Monopoly power is defined "as the power to control prices in the relevant market or to exclude competitors." *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 596, n.20 (1985). The critical inquiry is whether Schering had monopoly power in the relevant market at the time it entered the challenged agreements. Bresnahan, Tr. 659-60. Complaint Counsel asserts that Schering must have had monopoly power because it otherwise would not have paid Upsher-Smith and ESI not to enter the market. This circular argument is not evidence to support a finding of monopoly power. *See Interpreters*, 123 F.T.C. at 642 (the fact that some members charged the agreed upon price does not necessarily mean that they have market power).
Instead, monopoly power is determined through an analysis of market shares, barriers to entry and the ability of rivals to expand output in that market. *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995).

a. Market share

Complaint Counsel presented insufficient evidence on Schering's market share in the market for all oral potassium supplements. Schering's share of the market for potassium supplements between 1995 and 1999 was between 30 and 40 percent. F. 400-04. Schering's market share of less than 50 percent cannot as a matter of law support an inference of monopoly power. *See, e.g., Bailey v. Allgas, Inc.*, 284 F.3d 1237, 1250 (11th Cir. 2002) ("A market share at or less than 50% is inadequate as a matter of law to constitute monopoly power"); *Blue Cross & Blue Shield United v. Marshfield Clinic*, 65 F.3d 1406, 1411 (7th Cir. 1995) ("50 percent is below any accepted benchmark for inferring monopoly power from market share").

b. Lack of barriers to entry and the ability of rivals to expand output

Complaint Counsel did not prove high entry barriers into the market for all oral potassium chloride supplements. The evidence demonstrates that there were over 30 products competing as of 1997 in the potassium chloride market, all of which had entered at some point, and that a number of new competitors entered the market in recent years. F. 405-08. Absent evidence of high entry barriers, an inference of monopoly power is inappropriate. *See, e.g., Western Parcel Express v. UPS, Inc.*, 190 F.3d 974, 977 (9th Cir. 1999) ("'A high market share, though it may ordinarily raise an inference of monopoly power, will not do so in a market with low entry barriers or other evidence of a defendant's inability to control prices or exclude competitors'") (citations omitted). Complaint Counsel did not prove the inability of other firms to expand output in the face of a price increase or output reduction by Schering. F. 405-08. When firms can rapidly expand output, as here, an inference of monopoly power is inappropriate. *See, e.g., Rebel Oil Co.*, 51 F.3d at 1441 (power over price "depends largely on the ability of existing firms to quickly increase their own output in response to a contraction by the defendant").

c. Pricing

Contrary to Complaint Counsel's contention, pricing above marginal cost does not establish monopoly power or market power. *See* I Herbert Hovenkamp and Mark A. Lemley, *IP and Antitrust* § 4.1c, at 4-5 thru 4-7 (Aspen Law & Business 2002) (use of marginal cost "for measuring power is very hard to make workable in the case of intellectual property"); *see id.* at 4-9 ("the underlying theory of intellectual property rights is that an anticipated stream of above cost prices creates the incentive to engage in research or creativity in the first place") Even if it could, Complaint Counsel failed to prove that K-Dur was sold above marginal cost for extended periods of time. The fact that someone could undersell K-Dur 20 does not prove that contention, and Complaint Counsel offered no other evidence.

Further, higher prices for a branded product do not establish monopoly power. *SMS Sys. Maintenance Serv., Inc. v. Digital Equip. Corp.*, 188 F.3d 11, 17 (1st Cir. 1999) ("In any market with some degree of product differentiation, goods of a single brand will enjoy a certain degree of uniqueness. . . , that fact, without more, does not suffice to establish that the manufacturer enjoys monopoly power in that market."), *cert. denied*, 528 U.S. 1188 (2000). Evidence of higher prices is ambiguous at best, and insufficient evidence of monopoly power in the absence of market analysis. *Tarrant Serv. Agency v. Am. Standard, Inc.*, 12 F.3d 609, 615 (6th Cir. 1993) (higher prices for genuine parts was not evidence of monopoly power in market that included generic parts).

Complaint Counsel asserts that it proved monopoly power because Schering priced K-Dur 20 at an elevated price. Pricing evidence alone is not sufficient to prove monopoly power. *See, e.g., Forsyth v. Humana, Inc.*, 114 F.3d 1467, 1476 (9th Cir. 1997) (evidence that firm "routinely charged higher prices than [competitors] while reaping high profits" did not constitute "direct evidence of market

power" because there was no evidence of "restricted output"); *Blue Cross & Blue Shield*, 65 F.3d at 1411-12 (higher prices "may reflect a higher quality more costly to provide . . . it is always treacherous to try to infer monopoly power from a high rate of return"); *In re IBM Peripheral EDP Devices Antitrust Litig.*, 481 F. Supp. 965, 981 (N.D. Cal. 1979), *aff'd* 698 F.2d 1377 (9th Cir. 1983) ("[The inference that a defendant that enjoys healthy profits only does so because of an unhealthy market structure is not a strong one. Good management, superior efficiency and differences in accounting provide explanations that are just as plausible, and none of those explanations is inconsistent with an effectively competitive market."). In this case, as in *Forsyth*, it is conceded by Complaint Counsel that at all times Schering was expanding its output of K-Dur 20. F. 409-13. Also, Schering had no ability to restrict the output of the more than 20 other firms selling "therapeutically equivalent" potassium chloride supplements. F. 408.

In addition, Complaint Counsel did not prove that Schering's pricing was at a monopoly level. Complaint Counsel's expert witness did not conduct a thorough examination of Schering's prices. Professor Bresnahan did not have a data set of Schering's prices or of competitors pricing; thus he could not compute the relative price level of K-Dur 20 to other products. F. 419 Professor Bresnahan did no study of costs so he is unable to evaluate the price increases for K-Dur 20. F. 423. Professor Bresnahan's failure to study competitive product pricing means that he cannot demonstrate that any price increase of K-Dur 20 over a 5 year period was more or less than the price increases of competitive potassium products. F. 423.

Complaint Counsel also asserts that the failure to lose sales despite a price rise to be evidence of a monopoly. This is not sufficient evidence to prove monopoly power. The price of K-Dur 10 rose every time that the price of K-Dur 20 rose. F. 101-03. And K-Dur 10 was at all times more expensive per dose that K-Dur 20. F. 101-03. By this logic, K-Dur 10 should be a "monopoly." Both Professor Bresnahan and Dr. Addanki refused to conclude that K-Dur 10 was a separate "monopoly" unto itself. F. 101-03.

A single firm's price increase data without data from other firms is not helpful. Without knowing systematically what the other firms were doing on price, it is impossible to know the relative price of K-Dur 20 to other firm's products. Nor is it possible to discern if product costs or firm costs are rising. And net pricing — considering rebates, allowances and free goods — was also missing from this analysis. These critical aspects of Schering's K-Dur pricing were not studied by Professor Bresnahan. F. 418- 29. A strong common feature of K-Dur 10 and K-Dur 20 was the heavy promotion of both products by Schering. F. 80. *See Levine*, 72 F.3d at 1552 (price increases do not prove actual direct effects without competitors' pricing and costs being examined).

d. Sensitivity to promotion and advertising

Professor Bresnahan conceded that Schering's advertising increased demand for potassium chloride and in particular K-Dur 20. Ray Russo testified that potassium chloride was highly sensitive to

promotions. Schering outspent branded potassium competitors such as Upsher-Smith by more than 100 to 1. F. 427. These levels of advertising were tremendous relative to the size of the potassium marketplace. F. 79-80; Russo, Tr. 3418-19 ("these are relatively I think promotion-sensitive markets. . . . We invested heavily in field force effort . . . we had a number of significant promotional programs over that approximate ten-year period that heavily promoted and marketed K-Dur – K-Dur 10 and K-Dur 20").

The fact that Schering's sales increased during the 1994 – 2000 period attests to the power of Schering's detailing and rebate activity. In fact, the approximately $200 million spent by Schering on rebates alone between 1995 and summer 2001 attests to the stiff competition Schering faced prior to the advent of AB-rated substitutes. F. 114-16. Schering also invested millions in promotion. F. 412.

Pharmaceutical promotions are pro-competitive, and Professor Bresnahan testified that aggressive marketing such as that practiced by Schering was not anticompetitive. Yet Professor Bresnahan made no attempt to assess the role of advertising on demand in this case or the relative strength of advertising efforts by potassium firms. Professor Addanki did so and found strong and pronounced effects from Schering's advertising. F. 411-13. Schering's executives recognized that marketing was the key to gaining market share from the other potassium firms: "Detailing by sales representatives is the most effective way to educate providers on the importance of K-DUR and move market share." CX 18 (1997 K-DUR Marketing Plan, Sept. 10, 1996 at SP 23 00039). F. 411-13.

e. K-Dur 10 sales demonstrate that K-Dur 20 was not a monopoly

K-Dur 10 in June 1997 amounted to 5% of the total prescriptions for potassium chloride in the United States. F. 101. Even if the 10 mEq segment were studied in isolation, K-Dur 10 had less than 9% of new prescriptions of 10 mEq strength potassium chloride. USX 626 at USL 15232 (listing more than 19 10 mEq strength potassium supplements; K-Dur 10 had 8.7% of NRx in 1996). F. 101.

Yet, despite K-Dur 10's non-monopoly status, K-Dur 10 sales performed just as Schering's K-Dur 20 performed. K-Dur 10's sales rose over time due to Schering's promotions. Despite the price increases for K-Dur 10, K-Dur 10's sales rose and in fact rose faster than K-Dur 20's sales. F. 101. K-Dur 10 demonstrates that avowedly non-monopoly branded products will perform in exactly the same way that K-Dur 20 performed when it is promoted.

f. Generic potassium products grew at a faster rate than K-Dur 20

Generic potassium – rather than branded potassium – grew at a faster rate than K-Dur 20, demonstrating the price sensitivity of many potassium purchasers. F. 402. Complaint Counsel assert that the sales of K-Dur 20 grew rapidly in the 1997-2000 period, implying that K-Dur 20 outsold all competing potassium despite price increases. The market share of generic potassium chloride rose as fast or faster than K-Dur 20 in every year from 1997 through 2000. F. 402. However, at the time

relevant to the Bresnahan test, June 1997, generic potassium tablets/capsules were almost as large in market share as all of K-Dur 20, 31.0% of total potassium chloride prescriptions. F. 402. With K-Dur 20 at 33.0% of total potassium chloride prescriptions, *id.*, other brands of potassium chloride, such as K-Tab, Micro K, Micro-K 10, Klotrix, Kaon-Cl, Klotrix, Klor Con 8 and Klor Con 10, accounted for 27.6% of total potassium chloride prescriptions as of June 1997. Ray Russo testified that generics were a major competitor to K-Dur due to substitution. F. 402.

2. Complaint Counsel Did Not Prove the Requisite Specific Intent for a Conspiracy to Monopolize the Market for Potassium Supplements

"Specific intent to monopolize is the heart of a conspiracy charge." *Salco Corp. v. Gen. Motors Corp.*, 517 F.2d 567, 576 (10th Cir. 1975). It is more demanding than the general-intent requirement of Section 1 claims. *See, e.g., Wagner v. Magellan Health Servs., Inc.*, 121 F. Supp. 2d 673, 681 (N.D. Ill. 2000) ("A conspiracy to monopolize under Section 2 is somewhat different than its Section 1 counterpart because of its heightened intent element, i.e., concerted action by knowing participants who have a specific intent to achieve a monopoly"). As one court recently stated, 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*. (citation omitted).

A mere confluence of economic interests between the parties does not establish a specific intent to monopolize. *See Building Indus. 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"); *Genetic Sys. Corp. v. Abbott Labs.*, 691 F. Supp. 407, 422 (D.D.C. 1988) (rejecting theory that "mutual purposes and intended effects" could satisfy specific intent standard) (citation omitted).

There is insufficient evidence to demonstrate that Upsher-Smith or Schering "specifically intended" to further Schering's alleged unlawful monopoly in the sale of K-Dur 20. Moreover, there were numerous legitimate business justifications offered for Upsher-Smith's and Schering's conduct, including ending the expensive and acrimonious patent litigation, obtaining a date certain for entry of Upsher-Smith's generic product five years before the expiration of Schering's patent, opening the door for other generic mEq sustained-release potassium chloride supplements to enter the market, freeing up resources at Upsher-Smith for future pharmaceutical R&D and marketing of potassium products; and giving Upsher-Smith overseas distribution capability for six of its pharmaceutical products.

As the court in *Microsoft* explained, to establish a Section 2 conspiracy, "what plaintiffs must prove is that when confronted with Microsoft's demands, the OEM defendants stepped back and concluded that maintaining Microsoft's monopolies was a goal that they themselves desired to

accomplish." *Microsoft*, 127 F. Supp. 2d at 731. The credible evidence demonstrates that far from seeking to further Schering's alleged monopoly, Upsher-Smith fought hard to bring its product to market and competed vigorously with Schering before, during and after the execution of the settlement agreement.

IV. SUMMARY OF CONCLUSIONS OF LAW

2. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and over Respondents Schering-Plough Corporation ("Schering") and Upsher-Smith Laboratories, Inc. ("Upsher-Smith").

3. Schering is a corporation, as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

4. Schering's acts and practices, including the acts and practices alleged in the Complaint, are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission, 15 U.S.C. § 44.

5. Upsher-Smith is incorporated, has shares of capital or capital stock, and is authorized to carry on business for its own profit, and is, therefore, a corporation, as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

6. Upsher-Smith's business activities are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

7. Complaint Counsel bears the burden of proof of establishing each element of the violations of the Complaint.

8. The relevant geographic market for assessing the allegations of the Complaint is the United States.

9. The relevant product market for assessing the allegations of the Complaint is all oral potassium supplements that can be prescribed by a physician for a patient in need of a potassium supplement.

10. Complaint Counsel failed to prove or properly define the relevant product market.

11. Patent laws confer upon the patentee the exclusive right to make, use or sell the patented invention during the patent term, and authorize the patentee to exclude others – for example, by the initiation of infringement litigation – from manufacturing, using and/or selling the invention during the patent term.

12. The agreement between Schering Plough and Upsher-Smith did not unreasonably restrain competition and was not an unfair method of trade.

13. The agreement between Schering Plough and ESI did not unreasonably restrain competition and was not an unfair method of trade.

14. Schering-Plough does not have monopoly power in the relevant product market.

15. Schering-Plough did not engage in conduct to unlawfully preserve monopoly power in the relevant product market.

16. Schering-Plough did not conspire with Upsher-Smith or ESI to unlawfully preserve monopoly power in the relevant product market.

17. Complaint Counsel failed to meet its burden of proof in support of the Violations alleged in the Complaint.

18. The Complaint should be and is dismissed.

ORDER

For the reasons stated above,

IT IS ORDERED that all violations of the Complaint be, and hereby are, dismissed.

ORDERED:

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D. Michael Chappell
Administrative Law Judge

Dated: June 27, 2002