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IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

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ELEVENTH CIRCUIT
March 8, 2005
THOMAS K. KAHN
CLERK

No. 04-10688

Agency No. FTC 9297

SCHERING-PLOUGH CORPORATION,
UPSHER-SMITH LABORATORIES, INC.,
a Minnesota corporation having its
principal place of business in Minnesota,

Petitioners,

versus

FEDERAL TRADE COMMISSION,

Respondent.

Petitions for Review of a Decision of the
Federal Trade Commission

(March 8, 2005)

Before DUBINA and FAY, Circuit Judges, and GOLDBERG*, Judge.

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* Honorable Richard W. Goldberg, Judge, United States Court of International Trade, sitting by designation.

FAY, Circuit Judge:

Pharmaceutical companies Schering-Plough Corp. and Upsher-Smith Laboratories, Inc. petition for review of an order of the Federal Trade Commission ("FTC") that they cease and desist from being parties to any agreement settling a patent infringement lawsuit, in which a generic manufacturer either (1) receives anything of value; and (2) agrees to suspend research, development, manufacture, marketing, or sales of its product for any period of time. The issue is whether substantial evidence supports the conclusion that the Schering-Plough settlements unreasonably restrain trade in violation of Section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and Section 5 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45(c). We have jurisdiction pursuant to 15 U.S.C. § 45(c), and, for the reasons discussed below, we grant the petition for review and set aside and vacate the FTC's order.

I. Factual Background

A. The Upsher Settlement

Schering-Plough ("Schering") is a pharmaceutical corporation that develops, markets, and sells a variety of science-based medicines, including antihistamines, corticosteroids, antibiotics, anti-infectives and antiviral products. Schering manufactures and markets an extended-release microencapsulated potassium chloride

product, K-Dur 20,which is a supplement generally taken in conjunction with prescription medicines for the treatment of high blood pressure or congestive heart disease. The active ingredient in K-Dur 20, potassium chloride, is commonly used and unpatentable. Schering, however, owns a formulation patent on the extended-release coating, which surrounds the potassium chloride in K-Dur 20, patent number 4,863,743 (the "'743 patent"). The '743 patent expires on September 5, 2006.[1]

In late 1995, Upsher-Smith Laboratories ("Upsher"), one of Schering's competitors, sought Food and Drug Administration ("FDA") approval to market Klor Con M20 ("Klor Con"), a generic version of K-Dur 20.[2] Asserting that Upsher's

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[1] Schering also markets another version of this product, K-Dur 10, the coating of which is also covered by the '743 patent. The difference between the two is dosage: K-Dur 20 contains twice as much potassium as K-Dur 10. This lawsuit only involves K-Dur 20.

The '743 patent claims a pharmaceutical dosage unit in tablet form for oral administration of potassium chloride. The tablet contains potassium chloride crystals coated with a cellulose-type material. The novel feature in the '743 patent is the viscous coating, which is applied to potassium chloride crystals. The coating provides a sustained-release delivery of the potassium chloride.

[2] The FDA must approve any new drug before it can be marketed or sold in the United States. Previously, applications for FDA approval proceeded under a new drug application ("NDA"). 21 U.S.C. § 355(b). This cumbersome and involved process required each applicant to submit safety and efficacy studies, even if it duplicated previous studies done on identical drugs with the same ingredients. In 1984, Congress passed Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984). The purpose of the Hatch-Waxman Act was threefold: (1) to reduce the average price paid by consumers; (2) preserve the technologies pioneered by the brand-name pharmaceutical companies; and (3) create an abbreviated new drug application ("ANDA") to bring generic drugs to the market.

The ANDA process allows the manufacturers of generic drugs to gain early entry into the market. Hatch-Waxman's truncated procedure avoids the duplication of expensive safety and efficacy studies, so long as the generic manufacturer proves that its drug is bio-equivalent to the

product was an infringing generic substitute, Schering sued for patent infringement. K-Dur 20 itself was the most frequently prescribed potassium supplement, and generic manufacturers such as Upsher could develop their own potassium-chloride supplement as long as the supplement's coating did not infringe on Schering's patent.

In 1997, prior to trial, Schering and Upsher entered settlement discussions. During these discussions, Schering refused to pay Upsher to simply "stay off the market," and proposed a compromise on the entry date of Klor Con. Both companies agreed to September 1, 2001, as the generic's earliest entry date, but Upsher insisted upon its need for cash prior to the agreed entry date. Although still opposed to paying Upsher for holding Klor Con's release date, Schering agreed to a separate deal to license other Upsher products. Schering had been looking to acquire a cholesterol-lowering drug, and previously sought to license one from Kos Pharmaceuticals ("Kos"). After reviewing a number of Upsher's products, Schering became particularly interested in Niacor-SR ("Niacor"), which was a sustained-release niacin

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already-approved brand-name/pioneer drug. As part of the application process, the generic applicant must certify that the relevant patent(s) on the brand-name drug are either invalid or will not be infringed. This is commonly known as a "Paragraph IV certification." The patent holder is then notified of the ANDA, and if the patent holder sues for infringement within forty-five days of receiving the notice, the FDA automatically institutes a thirty-month delay on the generic manufacturer's ANDA approval. See 21 U.S.C. 355(j)(5)(B)(iii).

As part of its ANDA, Upsher certified that Schering's patent was either invalid or that Upsher did not infringe on that patent. When Schering brought suit, the thirty-month delay was activated.

product used to reduce cholesterol.[3]

Upsher offered to sell Schering an exclusive license to market Niacor worldwide, except for North America. The parties executed a confidentiality agreement in June 1997, and Schering received licenses to market five Upsher products, including Niacor. In relation to Niacor, Schering received a data package, containing the results of Niacor's clinical studies. The cardiovascular products unit of Schering's Global Marketing division, headed by James Audibert ("Audibert") evaluated Niacor's profitability and effectiveness.

According to the National Institute of Health, niacin was the only product known to have a positive effect on the four lipids related to cholesterol management. Immediate-release niacin, however, created an annoying - but innocuous - side effect of "flushing," which reduced patient compliance. On the other hand, previous versions of sustained-release niacin supplements, like Niacor, had been associated with substantial elevations in liver enzyme levels.

Schering knew of the effects associated with niacin supplements, but continued with its studies of Niacor because it had passed the FDA's medical review

[3] Schering's focus on Niacor is consistent with its previous attempt to purchase the rights to Niaspan, another sustained-release niacin product, which Kos was in the process of developing during this time. Negotiations between Kos and Schering broke down several months before Upsher offered Niacor to Schering.

and determined that it would likely be approved. More important, the clinical trials studied by Audibert demonstrated that Niacor reduced the flushing effect to one-fourth of the immediate-release niacin levels and only increased liver enzymes by four percent, which was generally consistent with other cholesterol inhibitors. Based on this data, Audibert constructed a sales and profitability forecast, and concluded that Niacor's net present value at that time would be between $245-265 million.

On June 17, 1997, the day before the patent trial was scheduled to begin, Schering and Upsher concluded the settlement. The companies negotiated a three-part license deal, which called for Schering to pay (1) $60 million in initial royalty fees; (2) $10 million in milestone royalty payments; and (3) 10% or 15% royalties on sales. Schering's board approved of the licensing transaction after determining the deal was valuable to Schering. This estimation corresponds to the independent valuation that Schering completed in relation to Kos' Niaspan, a substantially similar product to Niacor. That evaluation fixed Niaspan's net present value between $225-265 million.

The sales projections for both the Kos and Upsher products are substantially similar. Raymond Russo ("Russo") estimated Niaspan (Kos' supplement) sales to reach $174 million by 2005 for the U.S. market. Comparably, and more conseratively, Audibert predicted Niacor (Upsher's supplement) to reach $136 million for the global market outside the United States, Canada, and Mexico, which is either equal to or

larger than U.S. market alone.[4]

After acquiring the licensing rights to Niacor, Schering began to ready its documents for overseas filings. In late 1997, however, Kos released its first-quarter sales results for Niaspan, which indicated a poor performance and lagging sales. Following this announcement, Kos' stock price dramatically dropped from $30.94 to $16.56, and eventually bottomed out at less than $6.00. In 1998, with Niaspan's disappointing decline as a precursor, Upsher and Schering decided further investment in Niacor would be unwise.

B. The ESI Settlement

In 1995, ESI Lederle, Inc. ("ESI"), another pharmaceutical manufacturer, sought FDA approval to market its own generic version of K-Dur 20 called "Micro-K 20."[5] Schering sued ESI in United States District Court, and, as part of the pretrial process, the trial judge prompted the parties to engage a court-supervised mediation, pursuant to the Civil Justice Reform Act, 28 U.S.C. § 471 et seq. (1991). The trial court appointed U.S. Magistrate Judge Thomas Rueter ("Judge Rueter") to mediate

[4] Indeed, there is the indication of some internal independence between Schering's evaluation of Niaspan and Niacor, as two different teams examined the products and arrived at similar estimates.

[5] On December 22, 1995, ESI submitted an ANDA to the FDA that reference K-Dur 20 and contained a Paragraph IV certification to Schering's '743 patent. On December 29, 1995, ESI notified Schering of this certification containing data from a study demonstrating Micro-K 20's bioequivalency to Schering's K-Dur 20's tablets.

the fifteen-month process, which resulted in nothing more than an impasse.

Finally, in December 1997, Schering offered to divide the remaining patent life with ESI and allow Micro-K 20 to enter the market on January 1, 2004 - almost three years ahead of the patent's September 2006 expiration date.[6] ESI accepted this offer, but demanded on receiving some form of payment to settle the case. At Judge Rueter's suggestion, Schering offered to pay ESI $5 million, which was attributed to legal fees, however, ESI insisted upon another $10 million. Judge Rueter and Schering then devised an amicable settlement whereby Schering would pay ESI up to $ 10 million if ESI received FDA approval by a certain date. Schering doubted the likelihood of this contingency happening, and Judge Rueter intimated that if Schering's prediction proved true, it would not have to pay the $10 million.[7] The settlement was signed in Judge Rueter's presence on January 23, 1998.[8]

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[6] There was also a side agreement in this settlement that provided for a payment of $15 million in return for the right to license generic enalpril and buspirone from ESI..

[7] ESI provided Schering with information related to the Micro-K 20's current approval status. The summary noted the difficulties ESI had up to that point in trying to obtain FDA approval for its proposed generic version. The primary concern was ESI's bioequivalence study, which had been performed in 1989. The FDA found five different deficiencies with regard to that study, and ESI did not respond to those deficiencies until May 1997. ESI then began a new bioequivalence study in December 1997.

[8] Under the final settlement agreement, dated June 19, 1998, Schering agreed to pay ESI a $5 million noncontingent payment, representing legal fees, and an additional $10 million contingent on ESI's FDA approval. Schering and ESI also entered into a contemporaneous license agreement whereby ESI granted Schering the licenses to enalpril and buspirone in exchange for $15 million.

C. The FTC Complaint

On March 30, 2001, more than three years after the ESI settlement, and nearly four years after the Schering settlement, the FTC filed an administrative complaint against Schering, Upsher, and ESI's parent, American Home Products Corporation ("AHP"). The complaint alleged that Schering's settlements with Upsher and ESI were illegal agreements in restraint of trade, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The complaint also charged that Schering monopolized and conspired to monopolize the potassium supplement market.[9]

II. Procedural History

The Complaint was tried before an Administrative Law Judge (ALJ) from January 23, 2002 to March 28, 2002. Numerous exhibits were admitted in evidence, and the ALJ heard testimony from an array of expert witnesses presented by both sides. In his initial decision, the ALJ found that both agreements were lawful settlements of legitimate patent lawsuits, and dismissed the complaint. Specifically, the ALJ ruled that the theories advanced by the FTC, namely, that the agreements

[9] On October 12, 2001, the Complaint against AHP was withdrawn to consider a proposed consent agreement. The FTC approved a final consent order on April 2, 2002. AHP was not a party to either the trial before the ALJ or any subsequent proceedings, and is not a party to this appeal. The legality of the Schering's settlement with ESI/AHP, however, remained at issue with respect to Schering.

were anticompetitive, required either a presumption of (1) that Schering's '743 patent was invalid; or (2) that Upsher's or ESI's generic products did not infringe the '743 patent. The ALJ concluded that such presumptions had no basis in law or fact. Moreover, the ALJ noted that Schering's witnesses went unrebutted by FTC complaint counsel, and credibly established that the licensing agreement with Upsher was a "bona-fide arm's length transaction."

The ALJ further found that the presence of payments did not make the settlement anticompetitive, per se. Rather, the strength of the patent itself and its exclusionary power needed to be assessed. The initial decision highlighted the FTC's failure to prove that, absent a payment, either better settlement agreements or litigation results would have effected an earlier entry date for the generics. Finally, the ALJ found no proof that Schering maintained an illegal monopoly within the relevant potassium chloride supplement market.

The FTC's complaint counsel appealed this decision to the full Commission. On December 8, 2003, the Commission issued its opinion, reversing the ALJ's initial decision, and agreeing with complaint counsel that Schering's settlements with ESI and Upsher had violated the FTC Act and the Sherman Act. Although it refrained from ruling that Schering's payments to Upsher and ESI made the settlements per se illegal, the Commission concluded that the quid pro quo for the payment was an

agreement to defer the entry dates, and that such delay would injure competition and consumers.

In contrast to the ALJ's inquiry into the merits of the '743 patent litigation, the Commission turned instead to the entry dates that "might have been" agreed upon in the absence of payments as the determinative factor. Despite the Commission's assumption that the parties could have achieved earlier entry dates via litigation or non-monetary compromises, it also acknowledged that the settled entry dates were non-negotiable. Upon review of the settlement payments, the Commission determined that neither the $60 million to Upsher nor the $30 million to ESI represented legitimate consideration for the licenses granted by Upsher or ESI's ability to secure FDA approval of its generic.[10] Consequently, the Commission prohibited settlements under which the generic receives anything of value and agrees to defer its own research, development, production or sales activities. Nevertheless, the Commission carved out one arbitrary exception for payments to the generic: beyond a "simple compromise" to the entry date, if payments can be linked to litigation costs (not to exceed $2 million), and the Commission is notified of the settlement, then the parties

[10] The contradictory nature of the Commission's opinion is exemplified by its assessment of the ESI settlement. Although the Commission found the payment to be unjustified and in violation of the law, it simultaneously explained that "[a]s a matter of prosecutorial discretion, we might not have brought a stand-alone case based on such relatively limited evidence."

need not worry about a later antitrust attack. Neither of the Schering agreements fit this caveat, and Schering and Upsher timely petition for review.

III. Standard of Review

We review the FTC's findings of fact and economic conclusions under the substantial evidence standard. 15 U.S.C. § 45(c); see Orkin Exterminating Co., Inc. v. FTC, 849 F.2d 1354 (11th Cir. 1988); Olin Corp. v. FTC, 986 F.2d 1295 (9th Cir. 1993). The FTC's findings of fact, "if supported by evidence, shall be conclusive." 15 U.S.C. § 45(c). This standard applies regardless whether the FTC agrees with the ALJ. Thiret v. FTC, 512 F.2d 176, 179 (10th Cir. 1975). We may, however, examine the FTC's findings more closely where they differ from those of the ALJ. Id.; California Dental Association v. FTC, 128 F.3d 720, 725 (9th Cir. 1997), rev'd on other grounds, 526 U.S. 756 (1990); see also ITT Continental Baking Co. v. FTC, 532 F.2d 207, 219 (2d Cir. 1976); American Cyanamid Co. v. FTC, 363 F.2d 757, 772-73 (6th Cir. 1966). "Substantial evidence is more than a mere scintilla," and we require "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229, 83 L. Ed. 126, 59 S. Ct. 206 (1938); Consolo v. Federal Maritime Commission, 383 U.S. 607, 620, 86 S.Ct. 1018, 1026, 16 L.Ed.2d 131 (1966); see NLRB v. Gimrock Constr., Inc., 247 F.3d 1307, 1309 (11th Cir. 2001).While we afford the FTC some deference as to its

informed judgment that a particular commercial practice violates the FTC Act, we review issues of law de novo. See FTC v. Indiana Federation of Dentists, 476 U.S. 447, 454, 106 S.Ct. 2009, 2015-16, 90 L.Ed.2d 445 (1986).

In their arguments, the parties urge that Universal Camera provides the yardstick by which to measure the evidence at issue. Indeed, in 1951, the Supreme Court clarified the substantial evidence standard for reviewing an administrative agency's decision. Universal Camera Corp. v. NLRB, 340 U.S. 474, 487-88, 95 L. Ed. 456, 71 S. Ct. 456 (1951). In Universal Camera, the ALJ found an employee was lawfully discharged for insubordination rather than his appearance at an NLRB proceeding. The factual testimony directly conflicted, and the ALJ's finding clearly relied on a credibility determination. The Board reversed the holding. On judicial review, the court of appeals hesitated to consider the ALJ's initial ruling because the Administrative Procedure Act gave the Board "all the powers it would have had in making the initial decision." 5 U.S.C. § 557(b). Thus, the Second Circuit affirmed the Board's decision. The Supreme Court disagreed, and held that the plain language of the statute required a review of the record as a whole, which included the ALJ's decision. Universal Camera, 340 U.S. at 493.

Although Universal Camera involved the NLRB, and not the FTC, the results are applicable here. When we review a jury verdict, we ignore all evidence contrary

to the verdict and then draw every reasonable inference in favor of the verdict from the remaining evidence. In the administrative setting, however, Universal Camera dictates that "the substantiality of the evidence must take into account whatever in the record fairly detracts from its weight." Id. at 488. We are mindful that we do not review the record to draw our own conclusions that we then measure against an administrative agency; rather, we must consider all of the evidence when drawing our conclusions about the reasonableness of an agency's findings of fact. The evidence must be such that it would be possible for a reviewing court to reach the same conclusions that the administrative fact-finder did. If this condition is not met, then the substantial evidence test requires that the administrative decision be reversed. Id.

IV. Discussion

The question remains whether the Commission's conclusions are legally sufficient to establish a violation of the Sherman Act and the FTC Act--that is, whether Schering's agreements with Upsher and ESI amount to an "unreasonable" restraint of trade. In Valley Drug, this Court stated that the "ultimate purpose of the antitrust inquiry is to form a judgment with respect to the competitive significance of the restraint at issue." Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1303-04 (11th Cir. 2003) (citing NCAA v. Bd. of Regents Okla. Univ., 468 U.S. 85, 103, 104 S.Ct. 2948, 2962, 82 L.Ed.2d 70 (1984)). We wrote that the focus of antitrust

analysis should be on "what conclusions regarding the competitive impact of a challenged restraint can confidently be drawn from the facts demonstrated by the parties." Valley Drug, 344 F.3d at 1304.

Valley Drug involved an interim settlement agreement between a patent-holding pharmaceutical company and its potential generic competitor. Under the agreement, the patent holder paid the generic manufacturer $4.5 million per month to keep its product off the market until resolution of the underlying patent infringement suit. The lower court determined that the payments amounted to a per se violation of antitrust laws. See In re Terazosin Hydrochloride Antitrust Litig., 164 F.Supp.2d 1340 (S.D. Fla. 2000). We reversed that decision, and concluded that monetary payments made to an alleged infringer as part of a patent litigation settlement did not constitute a per se violation of antitrust law. Valley Drug, 344 F.3d at 1309.

Although we acknowledged in Valley Drug that an agreement to allocate markets is "clearly anticompetitive," resulting in reduced competition, increased prices, and a diminished output, we nonetheless reversed for a rather simple reason: one of the parties owned a patent. Id. at 1304. We recognized the effect of agreements that employ extortion-type tactics to keep competitors from entering the market. In the context of patent litigation, however, the anticompetitive effect may be no more

broad than the patent's own exclusionary power. To expose those agreements to antitrust liability would "obviously chill such settlements." Id. at 1309.

Both the ALJ and the Commission analyzed the Schering agreements according to the rule of reason analysis, albeit under two different methodologies. To the contrary, the district court in Valley Drug approached the agreements in that case from the perspective of whether they were a per se violation of antitrust laws. Under the Supreme Court's guidance, an alleged restraint may be found unreasonable either because it fits within a category of restraints that has been held to be "per se" unreasonable, or because it violates the so-called "Rule of Reason."[11] The rule of reason tests "'whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.'" FTC v. Indiana Federation of Dentists, 476 U.S. 447, 457, 106 S.Ct. 2009, 2017, 90 L.Ed.2d 445 (1986) (quoting Chicago Board of Trade v. United States, 246 U.S. 231, 238, 385 S.Ct. 232, 244 (1918)).[12]

[11] The majority of antitrust claims are analyzed under the rule of reason. State Oil Co. v. Kahn, 522 U.S. 3, 20 (1997). Courts generally determine the reasonableness of a particular agreeement by reference to the surrounding facts and circumstances under the rule of reason. Generally, a per se analysis is applied only in limited circumstances, and after experience and pattern establish that a particular class of restraint is manifestly anticompetitive. Broadcast Music, Inc. v. Columbia Broad. Sys,, Inc. U.S. 1, 9 (1979). Essentially, the per se rule should only be employed when the conduct has "pernicious effect on competition" and "lack[s]...any redeeming virtue." Continental T.V. Inc. v. GTE Sylvania Inc., 433 U.S. 36, 50 (1977).

[12] By and large, the construction of the rule of reason inquiry has remained unaltered since the Supreme Court first articulated it in Chicago Board of Trade v. United States, 246 U.S.

Both the ALJ's initial decision and the Commission's opinion rejected the *per se* approach, and instead employed the rule of reason. The traditional rule of reason analysis requires the factfinder to "weigh all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition." Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 49, 97 S.Ct. 2549, 2557, 53 L.Ed.2d 568 (1977). The plaintiff bears an initial burden of demonstrating that the alleged agreement produced adverse, anti-competitive effects within the relevant product and geographic markets, i.e., market power. See FTC v. Indiana Federation of Dentists, 476 U.S. 447, 460-61, 106 S.Ct. 2009, 2019, 90 L.Ed.2d 445 (1986).[13]

Once the plaintiff meets the burden of producing sufficient evidence of market power, the burden then shifts to the defendant to show that the challenged conduct

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231, 238, 38 S.Ct. 242, 244, 62 L.Ed. 683 (1918):

> [T]he court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts.

[13] Indiana Dentists noted an exception to the burden of proving market power: "Since the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, 'proof of actual detrimental effects, such as a reduction of output,' can obviate the need for an inquiry into market power, which is but a 'surrogate for detrimental effects.'" 476 U.S. at 460-61 7 (citing P. Areeda, Antitrust Law ¶ 1511, p. 429 (1986)).

promotes a sufficiently pro-competitive objective. A restraint on competition cannot be justified solely on the basis of social welfare concerns. See, e.g., National Society of Professional Engineers v. United States, 435 U.S. 679, 98 S.Ct. 1355, 55 L.Ed.2d 637 (1978) ; Indiana Dentists, 476 U.S. at 463, 106 S.Ct. at 2020. In rebuttal then, the plaintiff must demonstrate that the restraint is not reasonably necessary to achieve the stated objective. Bhan v. NME Hospitals, Inc., 929 F.2d 1404, 1413 (9th Cir.), cert. denied, 502 U.S. 994, 112 S.Ct. 617, 116 L.Ed.2d 639 (1991).

In the present case, the Commission emphasized that its rule of reason standard required a methodology different from that set out by the ALJ's initial decision. The Commission chided the ALJ's approach - which evaluated the strength of the patent, defined the relevant geographic and product markets, calculated market shares, and then drew inferences from the shares and other industry characteristics - as an inappropriate manner of analyzing the competitive effects of the parties' activities. Instead, the Commission's rule of reason dictated application of the Indiana Federation exception, in that complaint counsel need not prove the relevant market. See 476 U.S. 460-61. Rather, the FTC was only required to show a detrimental market effect. Thus, under the Commission's standard, once the FTC met the low threshold of demonstrating the anticompetitive nature of the agreements, it found that Schering and Upsher did not sufficiently establish that the challenged activities were

justified by procompetitive benefits. Despite the appearance that it openly considered Schering and Upsher's procompetitive affirmative defense, the Commission immediately condemned the settlements because of their absolute anti-competitive nature, and discounted the merits of the patent litigation. It would seem as though the Commission clearly made its decision before it considered any contrary conclusion.

We think that neither the rule of reason nor the *per se* analysis is appropriate in this context. We are bound by our decision in Valley Drug where we held both approaches to be ill-suited for an antitrust analysis of patent cases because they seek to determine whether the challenged conduct had an anticompetitive effect on the market. 344 F.3d 1294, 1311 n.27.[14] By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present. "What is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the

[14] On remand, the district court in Valley Drug still applied a per se analysis, and found those agreements to be illegal. See In re Terazosin Hydrochloride Antitrust Litigation, __ F.Supp.2d __ (S.D. Fla. 2005).We note that the case at bar is wholly different from Valley Drug. The critical difference is that the agreements at issue in Valley Drug did not involve final settlements of patent litigation, and, moreover, the Valley Drug agreements did not permit the generic company to market its product before patent expiration. On remand, the district court emphasized that the "[a]greement did not resolve or even simplify Abbott's patent infringement action... to the contrary, the Agreement tended to prolong that dispute to Abbott's advantage, delaying generic entry for a longer period of time than the patent or any reasonable interpretation of the patent's protections would have provided." In re Terazosin Hydrochloride Antitrust Litigation, __ F.Supp.2d __ (S.D. Fla. 2005). Given these material distinctions, the same analysis cannot apply.

extent to which the patent laws prevent antitrust liability for such exclusionary effects." Id. Therefore, in line with Valley Drug, we think the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects. Valley Drug, 344 F.3d at 1312.[15]

A. The '743 Patent

"A patent shall be presumed valid." 35 U.S.C. § 282. See e.g., Doddridge v. Thompson, 22 U.S. 469, 483 (1824) (holding that a patent is presumed valid until the contrary is shown); Sure Plus Mfg. Co. v. Kobrin, 719 F.2d 1114, 1117 (11th Cir. 1983) ("Congress recognized the expertise of the patent office on this matter when it provided for a legal presumption in favor of patent validity for any patent issued by the patent office."). Engrafted into patent law is the notion that a patent grant bestows the right to exclude others from profiting by the patented invention." Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980); see Valley Drug, 344 F.3d at

[15] The Commission wrote that it would neither address the exclusionary power of Schering's patent nor compare the patent's scope to the exclusionary effect of the settlements. Rather, the Commission grounds its decision in the untenable supposition that without a payment there would have been different settlements with both ESI and Schering, resulting in earlier entry dates: "we cannot assume that Schering had a right to exclude Upsher's generic competition for the life of the patent any more than we can assume that Upsher had the right to enter earlier. In fact we make neither assumption, but focus on the effect that Schering's payment had to Upsher was likely to have on the generic entry date which the parties would otherwise have agreed to in a settlement."

1304 ("A patent grants its owner the lawful right to exclude others."). Thus, the Patent Act essentially provides the patent owner "with what amounts to a permissible monopoly over the patented work." Telecom Technical Services Inc. v. Rolm Co., 388 F.3d 820, 828 (11th Cir. 2004) (citing Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 135, 89 S.Ct. 1562, 23 L.Ed.2d 129 (1969)). The Patent Act also explicitly allows for the assignability of a patent; providing the owner with a right to "grant or 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.

By virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products, Klor-Con and Micro-K 20, respectively, did not infringe Schering's patent. Although the exclusionary power of a patent may seem incongruous with the goals of antitrust law, a delicate balance must be drawn between the two regulatory schemes. Indeed, application of antitrust law to markets affected by the exclusionary statutes set forth in patent law cannot discount the rights of the patent holder. Simpson v. Union Oil Co., 377 U.S. 13, 14, 84 S.Ct. 1051, 12 L.Ed.2d 98 (1964). (Patent laws "are in pari materia with the antitrust laws and modify them pro tanto (as far as the patent laws go)."). Therefore, a patent holder does not incur antitrust liability when it chooses to exclude others from producing its patented work.

Valley Drug, 344 F.3d at 1305.

A patent gives its owner the right to grant licenses, if it so chooses, or it may ride its wave alone until the patent expires. Ethyl Gasoline Corp. v. United States, 309 U.S. 436, 456 (1940). What patent law does not do, however, is extend the patentee's monopoly beyond its statutory right to exclude. Mallinckrodt, Inc. v. Medipart, Inc. 976 F.2d 700, 708 (Fed. Cir. 1992); see also, United States v. Singer Mfg. Co., 374 U.S. 174, 196-197, 83 S.Ct. 1773, 10 L.Ed.2d 823 (1963) ("[B]eyond the limited monopoly which is granted, the arrangements by which the patent is utilized are subject to the general law.... [T]he possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly."). If the challenged activity simply serves as a device to circumvent antitrust law, then that activity is susceptible to an antitrust suit. Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc., 289 F.Supp.2d 986, 991 (N.D. Ill. 2003), In Asahi, Judge Posner gave an illustrative example of when certain conduct transcends the confines of the patent:

> Suppose a seller obtains a patent that it knows is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues its competitors, and settles the suit by licensing them to use its patent in exchange for their agreeing not to sell the patented product for less than the price specified in the license. In such a case, the patent, the suit, and the settlement would be devices--masks--for fixing prices, in violation of antitrust law.

Id.

It is uncontested that potassium chloride is the unpatentable active ingredient in Schering's brand-name drug K-Dur 20. Schering won FDA approval in 1986 to sell its K-Dur 20 tablets. Under the Hatch-Waxman scheme, in order for Upsher and ESI to obtain FDA approval to market their generic versions of an approved drug product like K-Dur 20, they simply needed to demonstrate that the drugs were bioquivalent, i.e., that the "active ingredient of the new drug is the same as that of the listed drug." 21 U.S.C. § 355(j)(2)(A)(ii)(I).[16] K-Dur 20's uniqueness, and hence the reason for a patent, is the time-release capsule that surrounds the potassium chloride. Because the patent only covers the individualized delivery method (the sustained-release formula), and not the active ingredient itself, it is termed a "formulation" patent.

No one disputes that the '743 patent gave Schering the lawful right to exclude infringing products from the market until September 5, 2006. Nor is there any dispute that Schering's agreement with Upsher gave it a license under the '743 patent to sell a microencapsulated form of potassium chloride more than five years before the expiration of the '743 patent.[17] Likewise, ESI gained a license under the '743 patent to sell its microencapsulated version more than two years before the '743

[16] In fact, Upsher received final FDA approval to market its Klor-Con generic version in November 1998. ESI followed suit, gaining FDA approval for Micro-K 20 in June 1999.

[17] Upsher began selling Klor Con M20 on September 1, 2001.

patent expired. Perhaps most important, and which the ALJ duly noted, is that FTC complaint counsel acknowledged that it could not prove that Upsher and ESI could have entered the market on their own prior to the '743 patent's expiration on September 5, 2006. This reinforces the validity and strength of the patent.

Although the FTC alleges that Schering's settlement agreements are veiled attempts to disguise a quid pro quo arrangement aimed at preserving Schering's monopoly in the potassium chloride supplement market, there has been no allegation that the '743 patent itself is invalid or that the resulting infringement suits against Upsher and ESI were "shams." Additionally, without any evidence to the contrary, there is a presumption that the '743 patent is a valid one, which gives Schering the ability to exclude those who infringe on its product. Therefore, the proper analysis now turns to whether there is substantial evidence to support the Commission's conclusion that the challenged agreements restrict competition beyond the exclusionary effects of the '743 patent. Valley Drug, 344 F.3d at 1306; see also In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F.Supp. 2d 188, 196 (E.D.N.Y. 2003).[18]

[18]It is patently obvious that the Commission's opinion did not employ this analysis; preferring, instead, to proceed through its laborious rule of reason framework, eventually branding the challenged restraints to be illegal horizontal market allocation agreements. The Commission was ostensibly silent with regard to the '743 patent, yet it cavalierly dismissed our holding in Valley Drug, stating that a determination on the merits of the underlying patent disputes was "not supported by law or logic."

B. The Scope of Schering's Agreements

1. The Upsher Settlement

The FTC's complaint characterized the agreements at the center of this contest as "horizontal market allocation agreements," whereby Schering reserved its sales of K-Dur 20 for several years, while Upsher and ESI refrained from selling their generic versions of K-Dur 20 during that same time period. Adding to the FTC's ire is the presence of "reverse payments," represented by settlement payments from the patent owner to the alleged infringer. The Commission ruled that the coupling of reverse payments with an agreement by the generics not to enter the market before a particular date, "raise[d] a red flag that distinguishes this particular litigation settlement from most other patent settlements, and mandates a further inquiry." Slip. Op. at 29.

In the context of Schering's settlement with Upsher, the FTC argues that the $60 million payment from Schering to Upsher was not a bona fide royalty payment under the licenses Schering obtained for Niacor and five other Upsher products. Instead, according to the FTC, the royalty payments constituted payoffs to delay the introduction of Upsher's generic. The FTC concedes that its position fails if it cannot prove a direct causal link between the payments and the delay.

The trial before the ALJ covered 8,629 pages of transcript, involved forty-one

witnesses, and included thousands of exhibits. The trial revealed that Schering personnel evaluated Niacor, and forecast its profit stream with a net present value of $225-265 million. Upsher itself had invested significant time and financial resources in Niacor. Moreover, Schering had a long-documented and ongoing interest in licensing an extended-release niacin product, as evidenced by its efforts to acquire Niaspan from Kos Pharmaceuticals.

Evidence at trial also demonstrated that the personnel who evaluated Niaspan's potential were unaware of the ongoing litigation between Upsher and Schering, and had little, if any, incentive to inflate Niacor's value. Indeed, many of the estimates in conjunction with the Niacor evaluation traced the independent conclusions of the team that evaluated Niaspan. Schering's witnesses corroborated the documentary evidence, and the ALJ found the $60 million payment to Upsher to be a bona fide fair-value payment.

The Commission chose to align its opinion with the two witnesses presented by the FTC. One witness, Dr. Nelson Levy ("Levy") was proffered as an expert in pharmaceutical licensing and valuation. He concluded that the $60 million payment was "grossly excessive," and that Schering's due diligence in evaluating Niacor fell astonishingly short of industry standards. Levy cited Upsher and Schering's post-settlement behavior, as proof of the agreement's artificial nature. We are troubled by

Levy's testimony. Interestingly, Levy arrived at his conclusions without performing a quantitative analysis of Niacor or any of the other Upsher products licensed by Schering. Additionally, Levy lacked expertise in the area of cholesterol-lowering drugs and niacin supplements. Finally, Levy's unpersuasive appraisal of the post-settlement behavior blatantly ignored the parties' ongoing communications and the fact that the niacin market essentially bottomed out. Although the Commission's opinion does not state that it in relying on Levy's testimony, it curiously mirrors each of Levy's conclusions.

The FTC also offered Professor Timothy Bresnahan ("Bresnahan") to prove that Schering's payment was not for the Niacor license. While Bresnahan neither challenged Niacor's sales projections nor discounted its economic value, Bresnahan nonetheless opined that the payment was for Upsher's delayed entry, and not Niacor. Bresnahan based his conclusions on his interpretation of the parties' subjective incentives to trade a payment for delay. Bresnahan specifically pointed to Schering's failed transactions with Kos and the lack of other competitors vying for Niacor as evidence that the payment was not connected to the license.

Like the Levy testimony, the Commission did not expressly adopt Bresnahan's theories, but his rationale and the Commission's conclusions became one and the same. The Commission is quite comfortable with assenting to Bresnahan's rather

amorphous "incentive" theory despite its lack of empirical foundation.[19] Unfortunately, Bresnahan's so-called incentives do not rise to the level of legal conclusions. We understand that certain incentives may rank high in these transactions, but it also true that the possibility of an outside impetus often lays dormant. The simple presence of economic motive weighs little on the scale of probative value. See Serfeez v. Jewel Food Stores, 67 F.3d 591, 600-01 (7th Cir. 1995) ("The mere existence of mutual economic advantage, by itself, does not tend to exclude the possibility of independent, legitimate action and supplies no basis for inferring a conspiracy.").

The ALJ rejected the FTC's experts, concluding that testimony from Schering's witnesses "provides direct evidence that the parties did not exchange money for delay." The Commission disagreed, and determined that Niacor was not worth $60 million. To prove its point, the Commission relied on somewhat forced evidence: (1) the unconvincing fact that doctors gave Kos' niacin product mixed reviews, causing Schering to value those profits at an apparently contemptible $254 million; (2) the meretricious argument that Schering's personnel did not adequately assess Niacor's

[19] While the Commission's opinion conspicuously notes that it does not "adopt his terminology," it nonetheless endorses Bresnahan's incentive analysis: "We agree that there are strong monetary incentives for the pioneer and the generic to share the pioneer's substantial profits until the expiration of the patent, rather than compete head-to-head. The existence of these strong incentives, standing alone, obviously does not amount to proof of a law violation, but it may help to resolve conflicting inferences."

safety;[20] (3) the Commission's questionable non-expert opinion that Schering should have done more due diligence;[21] (4) the Commission's belief that the European market - where Schering held the Niacor license - for a niacin product was less desirable than the U.S. market;[22] and (5) Schering's post-settlement decision to discontinue its Niacor efforts in light of the poor sales effected by Kos' Niaspan.[23]

To borrow from the Commission's own words, we think its conclusion that Niacor was not worth $60 million, and that settlement payment was to keep Upsher off the market is "not supported by law or logic." Substantial evidence requires a review of the entire record at trial, and that most certainly includes the ALJ's

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[20] In his testimony before the ALJ, Dr. Levy asserted that Niacor was toxic to the liver and criticized Schering for not taking liver biopsies on Upsher's clinical patients, who had long-since exited the trial program. Levy's later testimony revealed that he was not an expert in cholesterol-reducing drugs, and admitted that he "probably overstated" his opinion. The Commission's opinion emphasizes that it did not rely on Dr. Levy's testimony, yet again it arrives at the same conclusion, despite what we would presume to be a similar lack of knowledge in cholesterol-reducing drugs. It puzzles us that the Commission's opinion carefully traces Schering's due diligence and goes to great pains to highlight the intricate details, but still scolds Schering for not doing more.

[21] The Commission's opinion cited no authority for this assumption, but it also rejects "any suggestion that a reasonably adequate product review must necessarily take months, because the opportunity may no longer be on the table."

[22] This opinion was offered by a Kos official, who saw the U.S. market as "more appealing than the European market." Evidence shows, and even the FTC's experts agreed, that the worldwide market Schering had acquired rights to was at least as large as the U.S. market.

[23] Niaspan's sales were in fact disappointing. Market analysts predicted its 1999 sales to reach $169.3 million, and Schering's more conservative estimate calculated $101 million for the same year. In actuality, the sales were only $37.9 million.

credibility determinations and the overwhelming evidence that contradicts the Commission's conclusion. Universal Camera, 340 U.S. at 487-488, 496 (1951); see also Equifax Inc. v. FTC, 678 F.2d 1047, 1052 (11th Cir. 1982).

The ALJ made credibility findings based upon his observations of the witnesses' demeanor and the testimony given at trial. The Commission rejected these findings, and instead relied on information that was not even in the record. The Supreme Court has noted the importance of an examiner's determination of credibility, and explained that evidence which supports an administrative agency's fact-finding "may be less substantial when an impartial, experienced examiner who has observed the witnesses and lived with the case has drawn conclusions different from the [agency's]..." Id.[24] Additionally, the Court instructs that "[t]he findings of the examiner are to be considered along with the consistency and inherent probability of testimony." Id.

We think that this record consistently demonstrates the factors that Schering considered, and there is nothing to undermine the clear findings of the ALJ that this evidence was reliable. The Commission's finding that the "Upsher licenses were worth nothing to Schering" overlooks the very nature of the pharmaceutical industry

[24] At the time of the opinion in Universal Camera, an "examiner" performed the same functions as an ALJ.

where licenses are very often granted on drugs that never see the market.[25] Likewise, the essence of research and development is the need to encourage and foster new innovations, which necessarily involves exploring licensing options and selecting which products to pursue.

Finally, we note that the terms of the Schering-Upsher agreement expressly describes three payments totaling $60 million as "up-front royalty payments." The surrounding negotiations, trial testimony, and the record all evidence that both parties intended "royalty" to denote its traditional meaning: that Schering would pay Upsher for the licenses and production rights of Upsher's products. 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)). There is nothing to refute that these payments are a fair price for Niacor and the other Upsher products. Schering-Plough made a stand-alone determination that it was getting as much in return from these products as it was paying, and just because the agreement also includes Upsher's entry date into the potassium chloride supplement market, one cannot infer that the payments were solely for the delay rather than the licenses. See

[25] At trial, the FTC selected eight products that Schering had licensed from companies other than Upsher for comparative analysis. Five of those eight products were never marketed.

Valley Drug, 344 F.3d at 1309. Thus, the substantial and overwhelming evidence undercuts the Commission's conclusion that Schering's agreement with Upsher was illegal.

2. The ESI Settlement

The Commission separately addressed Schering's settlement with ESI. Although it purported to analyze this agreement under the same scheme as it did the Upsher settlement, there is far less development of the factual record to support the Commission's conclusion that the settlement was unreasonable. At trial, the FTC called no fact witnesses to testify about the ESI settlement, and its economic expert offered only brief testimony. The Commission's opinion itself spends little time on the ESI settlement, and begins with the recognition that the case is based on "relatively limited evidence." On the other hand, Schering produced experts who posited that Schering would have won the patent case, and that the ESI's January 1, 2004, entry date reasonably reflected the strength of Schering's case. The FTC did not rebut this testimony, but rather ignored it.

It seems the sole indiscretion committed in the context of the ESI settlement is the inclusion of monetary payments. The Commission ignored the lengthy mediation process, and insisted that the parties could have reached an alternative settlement with an earlier entry date. We do not pretend to understand the

Commission's profound concern with this settlement, but it takes particular exception to the $10 million payment, which was contingent on FDA approval of the generic product. The Commission also subtly questions the validity of the $5 million for legal costs. We might only guess that if the legal fee tallied $2 million - the arbitrary cap the Commission would allow for such settlements - it would not garner the same scrutiny.

The Commission, however, refused to consider the underlying patent litigation, and its certainty to be a bitter and prolonged process. All of the evidence of record supports the conclusion of the ALJ that this is not the case of a "naked payment" aimed to delay the entry of product that is "legally ready and able to compete with Schering." The litigation that unfolded between Schering and ESI was fierce and impassioned. Fifteen months of mediation demonstrates the doubt of a peaceful conclusion (or a simple compromise, as the Commission would characterize it).

That the parties to a patent dispute may exchange consideration to settle their litigation has been endorsed by the Supreme Court. 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"). Veritably, the Commission's opinion would leave settlements, including those endorsed and facilitated by a federal court, with little confidence. The general policy

of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits. Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1368 (Fed. Cir. 2001); Foster v. Hallco Manufacturing Co., 947 F.2d 469, 477 (Fed. Cir. 1991); Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976). Patent owners should not be in a worse position, by virtue of the patent right, to negotiate and settle surrounding lawsuits. We find the terms of the settlement to be within the patent's exclusionary power, and "reflect a reasonable implementation" of the protections afforded by patent law. Valley Drug, 344 F.3d at 1312.

C. The Anticompetitive Effects

Our final line of inquiry turns to whether these agreements were indeed an "unfair method of competition." The FTC Act's prohibition on such agreements encompasses violations of other antitrust law, including the Sherman Act, which prohibits agreements in restraint of trade.15 U.S.C. § 45(c); California Dental Ass'n., 526 U.S. at 763 n.3. In California Dental, the Supreme Court required that the anticompetitive effect cannot be hypothetical or presumed. Rather, the probe must turn to "whether the effects actually are anticompetitive." Id. at 775 n.12.

The restraints at issue here covered any "sustained release microencapsulated potassium chloride tablet." Such a specific clause - an "ancillary restraint" - is routine to define the parameters of the agreement and to prevent future litigation over what

may or may not infringe upon the patent. See Rothery Storage & Van Co. v. Atlas Van Lines, Inc., 792 F.2d 210, 224 (D.C. Cir. 1986) ("The ancillary restraint is subordinate and collateral in the sense that it serves to make the main transaction more effective in accomplishing its purpose."). Ancillary restraints are generally permitted if they are "reasonably necessary" toward the contract's objective of utility and efficiency. See Law v. NCAA, 134 F.3d 1010, 1019 (10th Cir. 1998).

The efficiency-enhancing objectives of a patent settlement are clear, and "[p]ublic policy strongly favors settlement of disputes without litigation." Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir. 1976). 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."). In order for a condition to be ancillary, an agreement limiting competition must be secondary and collateral to an independent and legitimate transaction. Rothery Storage, 792 F.2d at 224. Naturally, the restraint imposed must relate to the ultimate objective, and cannot be so broad that some of the restraint extinguishes competition without creating efficiency. Even restraints ancillary in form can in substance be illegal if they are part of a general plan to gain monopoly control of a market. United States v. Addyston Pipe & Steel Co., 85 F. 271, 282-83 (6th Cir. 1898). Such a restraint, then, is not ancillary.

Under the Schering-Upsher agreement, the scope of the products subject to the September 1, 2001 entry date demonstrate an efficient narrowness. No other products were delayed by the ancillary restraints contained in the agreements. The '743 patent claims a "controlled release [microencapsulated] potassium chloride tablet." The language in the Schering-Upsher agreement covers the identical reach of the '743 patent. There is no broad provision that detracts from the efficiency of settling the underlying patent litigation. Nevertheless, the Commission rejected the notion that the narrow restraints were legitimate and reasonable means of accomplishing the settlement, and refused to consider that this settlement preserved public and private resources, and that the resultant certainty ultimately led to more intense competition.

The Commission's opinion requires the conclusion that but for the payments, the parties would have fashioned different settlements with different entry dates. Although it claimed to apply a rule of reason analysis, which we disagree with on its own, the Commission pointedly states that it logically concluded that "quid pro quo for the payment was an agreement by the generic to defer entry date beyond the date that represents an otherwise reasonable litigation compromise." We are not sure where this "logic" derives from, particularly given our holding in Valley Drug. "It is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit...litigation is a much more costly mechanism to

achieve exclusion, both to the parties and to the public, than is settlement." Id. at 1309.

The Commission rationalizes its decision not to consider the exclusionary power of the patent by asserting that the parties could have attained an earlier entry without the role of payments. There is simply no evidence in the record, however, that supports this conclusion. The Commission even recognized that the January 1, 2004 entry date in the ESI settlement was "non-negotiable." For its part, Schering presented experts who testified to the litigation truism that settlements are not always possible. Indeed, Schering's experts agreed that ancillary agreements may be the only avenue to settlement.

The proposition that the parties could have "simply compromised" on earlier entry dates is somewhat myopic, given the nature of patent litigation and the role that reverse payments play in settlements. It is uncontested that parties settle cases based on their perceived risk of prevailing in and losing the litigation. Pre-Hatch-Waxman, Upsher and ESI normally would have had to enter the market with their products, incurring the costs of clinical trials, manufacturing and marketing. This market entry would have driven down Schering's profits, as it took sales away. As a result, Schering would have sued ESI and Upsher, seeking damages for lost profits and willful infringement. Assuming the patent is reasonably strong, and the parties then

settled under this scenario, the money most probably would flow from the infringers to Schering because the generics would have put their companies at risk by making infringing sales.

By contrast, the Hatch-Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from any possible infringement. See In re Ciprofloxacin Hydrochloride Antitrust Litigation, 261 F.Supp.2d 188, 251 (E.D.N.Y. 2003). Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Id. Because of the Hatch-Waxman scheme, ESI and Upsher gained considerable leverage in patent litigation: the exposure to liability amounted to litigation costs, but paled in comparison to the immense volume of generic sales and profits. This statutory scheme could then cost Schering its patent.

By entering into the settlement agreements, Schering realized the full potential of its infringement suit - a determination that the '743 patent was valid and that ESI and Upsher would not infringe the patent in the future. Furthermore, although ESI and Upsher obtained less than what they would have received from successfully defending the lawsuits (the ability to immediately market their generics), they gained more than if they had lost. A conceivable compromise, then, directs the consideration from the patent owner to the challengers. Id. Ultimately, the consideration paid to

Upsher and ESI was arguably less than if Schering's patent had been invalidated, which would have resulted in the generic entry of potassium chloride supplements.

In fact, even in the pre-Hatch-Waxman context, "implicit consideration flows from the patent holder to the alleged infringer." Id. If Schering had been able to prove damages from infringing sales, and settled before trial for a sum less than the damages, the result is a windfall to the generic manufacturers who essentially keep a portion of the profits. If this were true, then under the Commission's analysis, such a settlement would be a violation of antitrust law because the infringer reaped the benefit of the patent holder's partial surrender of damages. Like the reverse payments at issue here, "such a rule would discourage any rational party from settling a patent case because it would be an invitation to antitrust litigation." Id.

The Commission's inflexible compromise-without-payment theory neglects to understand that "[r]everse payments are a natural by-product of the Hatch-Waxman process." Id. Pure compromise ignores that patents, payments, and settlement are, in a sense, all symbiotic components that must work together in order for the larger abstract to succeed. As Judge Posner emphasized in Asahi, "[i]f any settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus classified as involving a forbidden 'reverse payment,'

we shall have no more patent settlements." Asahi Glass Co.. 289 F.Supp. 2d at 994. We agree. If settlement negotiations fail and the patentee prevails in its suit, competition would be prevented to the same or an even greater extent because the generic could not enter the market prior to the expiration of the patent. See In re Ciprofloxacin Hydrochloride Antitrust Litigation, 261 F.Supp.2d 188, 250-52 (E.D.N.Y.2003). A prohibition on reverse-payment settlements would "reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive." Ashai Glass Co., 289 F.Supp. 2d at 994.

There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation. See generally D. Crane, "Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications," 54 Fla. L. Rev. 747, 760 (2002). Patent litigation breeds a litany of direct and indirect costs, ranging from attorney and expert fees to the expenses associated with discovery compliance. Other costs accrue for a variety of reasons, be it the result of uncompromising legal positions, differing strategic objectives, heightened emotions, lawyer incompetence, or sheer moxie. Id.; see also, S. Carlson, Patent Pools and the Antitrust Dilemma, 16 Yale. J. Reg. 359, 380 (1999) (U.S. patent litigation costs $1 billion annually).

Finally, the caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product. The intensified guesswork involved with lengthy litigation cuts against the benefits proposed by a rule that forecloses a patentee's ability to settle its infringement claim. See In re Tamoxifen Citrate Antitrust Litig., 277 F.Supp.2d 121, 133 (E.D.N.Y.2003) (noting that the settlement resolved the parties' complex patent litigation, and in so doing, "cleared the field" for other ANDA filers). Similarly, Hatch-Waxman settlements, likes the ones at issue here, which result in the patentee's purchase of a license for some of the alleged infringer's other products may benefit the public by introducing a new rival into the market, facilitating competitive production, and encouraging further innovation. See H. Hovenkamp, et al., Anticompetitive Settlement of Intellectual Property Disputes 87 Minn. L.Rev. at 1719, 1750-51 (2003); see also H. Hovenkamp Antitrust Law: An Analysis of Antitrust Principles and Their Application, ¶ 1780a (1999).

Despite the associated benefits of settlements - which include the avoidance of the burdensome costs and the resolution of uncertainty regarding the respective rights and obligations of party litigants - the Commission manufactured a rule that

would make almost any settlement involving a payment illegal.[26] Furthermore, the Commission's minimal allowance for $ 2 million in litigation costs is rather naive. While we agree that a settlement cannot be more anticompetitive than litigation, see Valley Drug, 344 F.3d at 1312, we must recognize "[a] suitable accommodation between antitrust law's free competition requirement and the patent regime's incentive system." 344 F.3d at 1307.

We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the "asymmetrics of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement." Id. at 1310. An exception cannot lie, as the Commission might think, when the issue turns on validity (Valley Drug) as opposed to infringement (the Schering agreements).[27] The effect is the same: a generic's entry into the market is delayed. What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection. Id. Here, we find that the agreements fell well within the protections of the '743 patent, and were therefore not

[26] Directly contrary to our opinion in Valley Drug.

[27] The Schering agreements would necessarily be stronger than those in Valley Drug, where the facts demonstrated the likelihood of an invalid patent, because a valid patent could operate to exclude all infringing products for the life of the patent.

illegal.

V. Conclusion

Valley Drug established the law in our Circuit. Simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannotbe the sole basis for a violation of antitrust law. This alone underscores the need to evaluate the strength of the patent. Our conclusion, to a degree, and we hope that the FTC is mindful of this, reflects policy. Given the costs of lawsuits to the parties, the public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements, we fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic's entry date, and, in an ancillary transaction, pays for other products licensed by the generic. Such a result does not represent the confluence of patent and antitrust law. Therefore, this Court grants the petition for review. Accordingly, we SET ASIDE the decision of the Federal Trade Commission and VACATE its cease and desist order.