Nos. 10-2077, 10-2078, 10-2079

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

IN RE K-DUR ANTITRUST LITIGATION

On Appeal from the United States District Court
for the District of New Jersey

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PLAINTIFFS-APPELLANTS

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STATEMENT OF INTEREST AND APPEALS ADDRESSED

The Department of Justice is responsible for enforcing the federal antitrust laws and has a strong interest in the correct application of those laws. That interest is particularly strong in cases challenging settlements of pharmaceutical patent disputes because these settlements significantly affect consumer welfare. In three such cases, the Supreme Court invited the views of the United States regarding petitions for certiorari, and the United States Court of Appeals for the Second Circuit invited the views of the United States in a fourth. The appeals by the plaintiffs-appellants here address the antitrust analysis appropriate to such cases, and this brief addresses only that analysis.

The United States files pursuant to the first sentence of Rule 29(a), Fed. R. Civ. P.

STATEMENT

1. This case arose in the context of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act" or the "Act"), Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C.); *see* App. Vol. 1 (attached to Appellants' Br.) ("A-_") A-11, A-14-17 (Special Master's Amended

Report and Recommendation) ("R&R"). The Act establishes procedures designed to facilitate the entry of lower-priced generic versions of existing brand-name drugs while maintaining incentives to invest in new drug development. Firms seeking approval from the Food and Drug Administration (FDA) to market new drugs have long been required to file a New Drug Application (NDA) demonstrating the safety and efficacy of a new product. 21 U.S.C. 355(b). Under the Hatch-Waxman Act, the NDA applicant must list with the FDA any patent that might reasonably be asserted against the unauthorized manufacture, sale, or use of the drug. 21 U.S.C. 355(b)(1)(G). A firm seeking to market a generic version of an approved drug may file an Abbreviated New Drug Application (ANDA) demonstrating that its product is bioequivalent to the brand-name counterpart, 21 U.S.C. 355(j), without independently demonstrating safety and efficacy.

If the branded drug is subject to one or more listed patents, the FDA cannot approve an ANDA before patent expiration, unless the applicant certifies that the patent in question is invalid or the generic product does not infringe it (a "paragraph IV certification"). 21 U.S.C. 355(j)(2)(A)(vii)(IV). The Act permits the generic drug firm to conduct

tests to develop information for an ANDA without infringing listed patents, but provides that the filing of a paragraph IV certification is an act of patent infringement, 35 U.S.C. 271(e)(1)-(2), of which the ANDA applicant must notify the patent owner and NDA applicant. 21 U.S.C. 355(j)(2)(B). Thus, a generic drug firm may be sued for infringement before it has undertaken activities creating a potential for significant damage liability. The Act encourages infringement suits within 45 days of a paragraph IV notification by providing that such timely filing automatically stays the effective date of FDA approval of the ANDA for 30 months (or less if the patents expire or are judicially determined to be invalid or not infringed before then). 21 U.S.C. 355(j)(5)(B)(iii). And the statute encourages ANDAs by granting a first ANDA filer with a paragraph IV certification relating to a listed patent on a particular drug the opportunity to market a generic version for 180 days without competition from later ANDA applicants. This "exclusivity" may begin with commercial marketing.

2. Market introduction of a generic drug has unique and dramatic economic consequences, because generics are significantly lower-priced bioequivalents of branded drugs and substitution is spurred by state

"generic substitution laws." These consequences create strong incentives for the branded drug manufacturer to pay a paragraph IV ANDA filer to settle the patent infringement litigation (that is, to make a "reverse" or "exclusion" payment). The branded firm faced with a generic firm's paragraph IV certification runs the risk that pursuing infringement litigation to a conclusion will result in a determination that its patent is invalid, *see In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 207, 209 (2d Cir. 2006), or not infringed, in either case resulting in competition from a lower-priced bioequivalent product and significantly lower profits. Moreover, the branded firm, unlikely to recover significant damages, has little to gain from winning a litigated judgment if it can protect the lucrative status quo by settlement. Indeed, although an unfavorable judgment as to invalidity will prevent the branded firm from excluding any future challenger, and one as to infringement would clear the way for other challengers with similar products, a favorable judgment will not preclude other would-be entrants from challenging the patent. *See Blonder-Tongue Labs. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971).

The generic drug firm accused of infringement typically can lose little out of pocket through litigation – principally, litigation costs – because it is unlikely either to be liable for damages or to have incurred substantial costs in preparing to market its product, *Tamoxifen*, 466 F.3d at 206-07, although it would be denied the fruits of victory. If, on the other hand, it wins a favorable judgment, those fruits for a first ANDA filer include the right to market its drug with a 180-day period of freedom from other generic competition (which may give it a lasting competitive advantage over subsequent generic entrants, *id.* at 207 n.19). Yet that may not be the generic firm's most favorable outcome.

Significantly, if the generic challenger wins, "the *total* profits of the patent holder and the generic manufacturer on the drug in the competitive market will be *lower* than the total profits of the patent holder alone under a patent-conferred monopoly." *Tamoxifen*, 466 F.3d at 209. Thus it may "make economic sense for the patent holder to pay some portion of that difference to the generic manufacturer to maintain the patent-monopoly market for itself." *Id.* And it may well make "economic sense for the generic manufacturer to accept such a payment if it is offered," agree to end its patent challenge, and not compete for

some or all of the remaining life of the patent, because the payment may be larger than its expected gain from continuing to litigate. *Id.* Indeed, the patent holder might be willing to pay more than the generic firm would stand to gain even if it prevailed in the litigation.

Despite recognizing the "troubling dynamic" of Hatch-Waxman reverse-payment settlements that "inevitably protect patent monopolies that are, perhaps, undeserved," 466 F.3d at 211, the Second Circuit held in *Tamoxifen* that such a settlement does not violate the antitrust laws unless (1) the settlement extends "the monopoly beyond the patent's scope," (2) the patent was procured by fraud, or (3) the infringement suit settled was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits," *Tamoxifen*, 466 F.3d at 213. It is in essence this standard that the court below adopted. A-56 (R&R) (determining to "apply an analysis consistent with the approach that has been adopted by the Second, Eleventh and Federal Circuits.").[1]

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[1]The Federal Circuit has endorsed a standard substantially identical to that of the Second Circuit, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1335-36 (Fed. Cir. 2008). Both courts read the Eleventh Circuit as having adopted a similar standard, *id.* at

3. This case is an antitrust challenge to an agreement settling patent litigation between defendant-appellee Schering-Plough Corp.[2] ("Schering") and defendant-appellee Upsher-Smith Laboratories, Inc. ("Upsher").[3] At relevant times, Schering marketed a potassium chloride supplement under the brand name K-Dur. The particular formulation of the supplement, but not the active ingredient, was protected by Schering's patent No. 4,863,743 (the "'743 patent"),[4] which expired in 2006. A-18 (R&R). In 1995, Upsher filed an ANDA for a bioequivalent generic version of K-Dur it called Klor-Con, with a paragraph IV certification explaining why, in its view, Klor-Con did not infringe the '743 patent. *Id.* at A-21-22.

1335; *Tamoxifen*, 466 F.3d at 212, in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), and the district court here evidently agreed.

[2]Since the events at issue here, Schering has merged with Merck & Co., Inc., and the merged firm uses the Merck name. We refer to the firm as Schering.

[3]The case includes a similar challenge to an agreement settling patent litigation between Schering and former defendant ESI-Lederle, Inc., with whom the plaintiffs have settled. A-18 n.10 (R&R). We focus on the Upsher agreement.

[4]The patent was owned by Key Pharmaceuticals, Inc., a division of Schering. We refer to the division as Schering.

Schering sued for infringement within the Hatch-Waxman 45-day limit. In 1997, Upsher moved for summary judgment of non-infringement. With trial scheduled to begin the next day, on June 17, 1997, the court held a hearing on, inter alia, the Upsher motion, A-23 (R&R), at which it "expressed doubt about Schering's infringement claim," *id.* at A-61.

Late that night, the parties reached a settlement. A-23-25 (R&R). It provided, inter alia, that Upsher would not market Klor-Con M20 "or any other sustained release microencapsulated potassium chloride tablet" before September 1, 2001, when it would receive from Schering a non-exclusive license to sell two potassium chloride supplements as Klor-Con products; that Upsher would grant Schering licenses to sell Niacor-SR (an unrelated drug) and five other Upsher products; and that Schering would pay Upsher $60 million. A-24-25 (R&R). Whether the payment was simply part of a license transaction separate from the settlement itself or instead was in whole or in part for Upsher's agreement to delay market entry is disputed.[5]

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[5]The Federal Trade Commission challenged the same agreements and found that "there was a direct nexus between Schering's payment

Various plaintiffs sued, alleging that the settlement agreement thus violated section 1 of the Sherman Act, 15 U.S.C. 1. On defendants' motion for summary judgment on all claims related to the Upsher agreement, the special master in essence adopted the Second Circuit's *Tamoxifen* standard. A-56 (R&R).[6]

Applying the standard, the special master concluded that the settlement agreement did not extend beyond the scope of the '743 patent even though it barred Upsher from marketing not only the allegedly infringing Klor-Con M20 product, but also "any other sustained release microencapsulated potassium chloride tablet," *id.*, whether or not alleged to infringe. The special master reasoned that

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and Upsher's agreement to delay its competitive entry and that the magnitude of the payment was not based on Schering's evaluation of the Upsher licenses." *In the Matter of Schering-Plough Corp.*, 136 F.T.C. 956, 1052 (2003) ("FTC Decision"), *vacated and set aside*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005). The FTC therefore concluded that Schering "did in fact pay Upsher for delayed entry." *Id.* The Eleventh Circuit disagreed, concluding that the "substantial" evidence was to the contrary. 402 F.3d at 1070-71. In this case, the district court did not resolve the dispute.

[6]The special master did not explicitly adopt the patent-procured-by-fraud branch of the standard; fraudulent procurement appears not to have been an issue.

the agreement could not on that basis be found to exceed the patent scope because there was no evidence that Upsher had or contemplated any such other product. A-56-57 (R&R). As for the allegedly infringing product itself, it did not literally infringe, and the plaintiffs argued that the doctrine of prosecution history estoppel and the all elements rule precluded using the doctrine of equivalents to expand the scope of the '743 patent to reach Upsher's product. *Id.* at A-57-58. The special master, however, considered it "inappropriate to conduct an *ex post* inquiry into infringement issues that were resolved by the parties' settlement," *id.* at A-54, and declined to conduct one, except under the remaining branch of the Second Circuit's test, objective baselessness. Under that heading, the special master concluded that these plaintiffs could not show objective baselessness on this, or any other, issue. *Id.* at A-61-62.

The district court adopted the special master's Report and Recommendations. A-9-10 (Order).

SUMMARY OF ARGUMENT

The Patent Act, 35 U.S.C. 1 *et seq.*, expressly grants patentees the right to enforce their patents through litigation but requires them to

accept the risk that exercising it will result in patent invalidation or a finding of no infringement. Although settlement of patent litigation is generally to be encouraged, settlements involving reverse payments substantially in excess of anticipated litigation costs may upset the balance Congress struck between the public interest in encouraging innovation and the public interest in competition. Reverse payments are scarcely essential to the voluntary settlement of patent disputes; to the contrary, they appear to be essentially unknown outside the Hatch-Waxman context.

Private agreements that include reverse payments are properly evaluated under the antitrust rule of reason, which takes into account efficiency-related justifications as well as anticompetitive potential. In the Hatch-Waxman context, the anticompetitive potential of reverse payments in exchange for the alleged infringer's agreement not to compete and to eschew any challenge to the patent is sufficiently clear that such agreements should be treated as presumptively unlawful under section 1 of the Sherman Act. Defendants may rebut that presumption by providing a reasonable explanation of the payment, so that there is no reason to find that the settlement does not provide a

degree of competition reasonably consistent with the parties' contemporaneous evaluations of their prospects of litigation success.

ARGUMENT

"Reverse Payment" Agreements That Delay Entry By A Potential Generic Competitor In Exchange For A Payment From A Branded Drug Manufacturer With Market Power Presumptively Violate The Sherman Act

A. Private Agreements Settling Litigation To Enforce A Patent Are Subject To Antitrust Scrutiny

1. Valid patents confer a right to exclude within their scope. Every issued patent must include "a grant to the patentee . . . of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States." 35 U.S.C. 154(a)(1). *See, e.g.*, *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) ("A patentee has the exclusive right to manufacture, use, and sell his invention."). The Patent Act authorizes the patentee to enforce that right to exclude by means of an action for infringement. 35 U.S.C. 281. *See Zenith*, 395 U.S. at 135 ("The heart of [a patentee's] legal monopoly is the right to invoke the State's power to prevent others from utilizing his discovery without his consent.").

Enforcement of a patent through litigation is privileged. Although an action for infringement is on its face an attempt to eliminate competition in a setting with limited competition, there is ordinarily no antitrust liability for bringing the action, *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 176-77 (1965), whatever its result.[7] Legitimate government petitioning, including the filing of a non-sham lawsuit, is immune from attack under the Sherman Act. *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.* 508 U.S. 49, 56-57 (1993). *See also* U.S. Const. amend. I ("Congress shall make no law . . . abridging . . . the right of the people peaceably . . . to petition the Government for a redress of grievances.").

Under the Patent Act, a defendant charged with infringement may assert the defenses of noninfringement, unenforceability, and invalidity. 35 U.S.C. 282. If the patent is adjudged to be invalid, the patentee loses not only the right to exclude the generic challenger with which it is in litigation, but also any other would-be entrant. *See Blonder-*

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[7] "The patent laws which give a [multi]-year monopoly on 'making, using, or selling the invention' are *in pari materia* with the antitrust laws and modify them *pro tanto*." *Simpson v. Union Oil Co. of Cal.*, 377 U.S. 13, 24 (1964).

Tongue Labs. v. Univ. of Ill. Found., 402 U.S. 313 (1971). Adverse determination of an infringement issue would have similar effects if the same issue arises in the patentee's subsequent litigation. Congress thus struck a balance in the Patent Act between (1) encouraging innovation by providing for the enforcement of legitimate patent rights, and (2) protecting consumers' interest in a competitive marketplace by providing for the invalidation of undeserved patents and the limitation of unwarranted patent scope. *Cf. Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly."). Moreover, Congress recognized that both the enforcement of patent rights and appropriate limits on the patentee's ability to exclude rivals have important roles to play in fostering innovation. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) ("From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.").

2. Patentees can avoid the litigation risks of an invalidity holding or a narrow reading of a patent's scope by settling infringement claims prior to judgment. Settlement of patent disputes, like voluntary resolution of other litigation, generally furthers the public interest by conserving the resources of the parties and the courts. The Patent Act does not, however, shield such private agreements from the possibility of antitrust liability.

Settlements, like all other private contracts, are subject to the antitrust laws. *Cf. Standard Oil Co. v. United States*, 283 U.S. 163, 169 (1931) ("The limited monopolies granted to patent holders do not exempt them from the prohibitions of the Sherman Act"). The Patent Act thus offers the patentee a choice between exercising its statutory privilege to protect its interests through infringement litigation – with the attendant litigation risks – and relying on private measures that avoid those risks but provide no antitrust immunity.

3. The standard adopted below inappropriately permits patent holders to contract their way out of the statutorily imposed litigation risks of invalidation or, as the district court applied it, narrowed scope while in effect claiming antitrust immunity for that private contract.

Except in instances of knowing fraud, objectively baseless infringement claims, or a settlement limiting competition beyond the scope of the patent, that standard treats a private settlement agreement excluding competition as the equivalent of a litigated judgment. Apart from these limited exceptions, this standard bars considering whether the agreement might violate the antitrust laws, and so offers no protection to the public interest in eliminating unwarranted restraints on competition. The *Tamoxifen* standard thus upsets the carefully crafted balance that Congress struck in the Patent Act. *See, e.g.*, *Edward Katzinger Co. v. Chi. Metallic Mfg. Co.*, 329 U.S. 394, 400 (1947) (noting the "necessity of protecting our competitive economy by keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid"); *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-01 (1993) (noting the "importance to the public at large of resolving questions of patent validity").

The district court's standard distorts the statutory process that leads to competition in the face of patent claims. This distortion has important consequences because there is a significant risk that a litigated judgment would result in earlier competition that a settlement

would bar. The Federal Trade Commission studied all patent litigations initiated between 1992 and 2000 between branded drug manufacturers and paragraph IV ANDA filers. It found that in the cases that were neither settled nor still pending in district court, the generic firm prevailed, by judgment of invalidity or non-infringement or by the patent holder's voluntary dismissal, in cases involving 73% of the drug products. FTC, *Generic Drug Entry Prior to Patent Expiration* 20 (July 2002), *available at* www.ftc.gov/os/2002/07/genericdrugstudy.pdf ("FTC Generic Drug Study"). In any event, patent litigation is inherently uncertain.

4. As noted above, *supra* pp. 3-6, the economics of generic competition and the legal structure created by Hatch-Waxman create unique incentives and opportunities for settlements that threaten the public interest, incentives and opportunities apparently not found elsewhere. Hatch-Waxman was plainly structured to identify the patents that blocked generic competition and to induce firms to challenge those patents, so that consumers might benefit from earlier generic entry. The consequences of settlements ending such challenges can be severe. Allowing the patent holder to claim antitrust immunity

for its private contracts as if they were litigated injunctions, while evading the risks of litigation, deprives consumers of significant benefits from price competition in the pharmaceutical industry.[8]

The Second Circuit acknowledged that the Hatch-Waxman Act creates "a troubling dynamic . . . . [W]eak patent cases will likely be settled even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved." *Tamoxifen*, 466 F.3d at 211. However, it discounted the seriousness of this concern, predicting that other generic firms would file paragraph IV ANDAs, and the patent holder likely could not buy all of them off. 466 F.3d at 211-12; *but see King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 521-22 (E.D. Pa. 2010) (drug manufacturer settled with four generic firms, which agreed to delay market entry "in exchange for significant payments . . . for various licensing agreements, supply agreements and research and development deals"). This discounting ignores important

[8]To simplify exposition, we assume that the patented drug at issue lacks substantial competition from other products so that the patent holder has monopoly power in a relevant market. While a large reverse payment may strongly suggest such power, market power cannot be presumed to follow from the existence of a patent, but must be proven. *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006).

aspects of the Hatch-Waxman context. The Act provides only the first paragraph IV ANDA filer the incentive of a 180-day exclusivity period. And even if this exclusivity did not block subsequent ANDA applicants, the time required to prepare an ANDA, combined with the 30-month automatic stay of FDA approval and the time required for litigation, could considerably delay market entry of subsequent filers. Moreover, the first paragraph IV ANDA filer may be uniquely positioned to challenge the patent holder's claims. Indeed, if a reverse payment settlement were so ineffective in excluding entry, it is hard to see why the patent holder would make the payment.

5. There is no sound basis for insulating private patent settlements from antitrust scrutiny. No statutory presumption of infringement exists. There is a statutory presumption of patent validity, 35 U.S.C. 282, but that presumption, "like all legal presumptions, is a procedural device, not substantive law," and serves only to assign burdens, *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983), in litigation challenging patent validity, *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985). Moreover, the presumption of patent validity is rebuttable. There is no basis for treating it as virtually conclusive and

allowing it to serve as a substantive basis for limiting the application of the Sherman Act, particularly since many litigated patents – notably in the Hatch-Waxman Act context – are held invalid. *See supra* pp. 16-17. The result is to treat all but the most obviously invalid patents as equally potent bulwarks against competition from generic drugs. This result seems particularly unacceptable when a substantial payment for an agreement to withdraw a patent validity challenge strongly implies that the payor recognized a significant risk of patent invalidation through litigation. And the result in this case – extending this presumption approach to patent settlements involving only infringement – lacks any basis whatever in the statute.

B. Private Agreements Settling Patent Litigation Are Not Unlawful Per Se, But Are Properly Evaluated Under The Rule of Reason

The settlement of a patent infringement case in the Hatch-Waxman context often involves an agreement not to compete. Naked agreements not to compete between actual or potential competitors are unlawful per se under section 1 of the Sherman Act. *See Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990) (per curiam); 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2030b, at 213 (2d ed. 2005) ("[T]he law does not condone the purchase

of protection from uncertain competition any more than it condones the elimination of actual competition."). Indeed, they are paradigmatic violations. Because of the patent, however, agreements settling patent litigation are not properly characterized as naked agreements not to compete.

Section 1 of the Sherman Act prohibits only agreements in "unreasonable" restraint of trade. *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997). Although infringement settlements may involve agreements not to compete, they may also serve efficiency-enhancing purposes. "[P]ublic policy wisely encourages settlements" of legal disputes, *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994), including patent disputes. Settlements not only conserve judicial resources, but they may allow the parties to avoid litigation costs. The vast majority of settlements in patent cases are likely to be efficiency enhancing and lawful. Moreover, the agreement not to compete may reflect merely an appreciation that competition would likely infringe a valid patent.

Accordingly, because the likelihood of anticompetitive effects not attributable solely to the patent is not so great as to "render unjustified further examination of the challenged conduct," *NCAA v. Bd. of Regents*

of Univ. of Okla., 468 U.S. 85, 103-04 (1984), per se condemnation of patent settlements under the Sherman Act is not justified. *See Tamoxifen*, 466 F.3d at 202 ("[w]here there are legitimately conflicting [patent] claims . . . , a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act." (quoting *Standard Oil*, 283 U.S. at 171)). Rather, such settlements are properly evaluated under the rule of reason, which takes account of potential justifications as well as anticompetitive effects. *See NCAA*, 468 U.S. at 98-104 (restraints on price and output competition analyzed under the rule of reason because of the potential justifications).

C. Settlements Involving A Payment In Exchange For An Agreement To Withdraw A Validity Or Non-Infringement Challenge And Limit Competition Are Presumptively Unlawful

1. In the Hatch-Waxman context as elsewhere, voluntary settlement of litigation is generally to be encouraged, and it can feasibly be accomplished through settlement terms that are unlikely to impair competition. Thus, if the parties settle a Hatch-Waxman suit by agreeing upon a date for a generic drug firm's entry prior to patent expiration, the agreement will reflect the parties' evaluations of their

likelihood of success in the patent litigation. The greater the perceived likelihood of the patent being held invalid or not infringed, the stronger the generic firm's bargaining position and the earlier the entry date it could achieve through negotiation. At least as a general matter, a settlement dividing the remaining life of the patent into a period of exclusion and a period of competition, based on the parties' expectations as to the likelihood of the possible litigation outcomes (and therefore their understanding of the value of a litigated outcome, on average) will adequately accommodate the public interest in freeing the market from undeserved monopolies.

Hatch-Waxman settlements that provide for substantial reverse payments from the patentee to the generic challenger, however, raise distinct concerns. Absent another explanation for it, such a payment is naturally viewed as consideration for the generic's agreement to delay entry beyond the point that would otherwise reflect the parties' shared view of the likelihood that the patentee would ultimately prevail in the

litigation. A payment in exchange for such additional exclusion is presumptively violative of section 1.[9]

Application of the rule of reason to Hatch-Waxman settlements calling for "reverse payments" in exchange for a generic drug manufacturer's agreement to withdraw its invalidity or non-infringement defense and delay entering the market need not involve an unduly complicated analysis. It is, of course, the antitrust plaintiff's ultimate burden to prove a reverse payment. If the plaintiff shows that the generic manufacturer withdrew its invalidity or non-infringement defense; that money (or other consideration serving the same purpose) flowed from the patent holder to the generic drug firm; and that the payment accompanied the agreement to withdraw these defenses,[10] it

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[9]Firms can and do settle Hatch-Waxman suits without reverse payments, *see* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 647-48 (2009), and such payments are essentially unknown in the settlement of other patent litigation.

[10]Naked reverse payments have "given way to more complex arrangements," *see* Hemphill, 109 Colum. L. Rev. at 663-66, making it difficult for an antitrust plaintiff to demonstrate a net flow of consideration to the generic firm. The evidence is in the hands of the defendants. As Professor Hemphill notes, because of "the absence of brand-generic deals outside of settlement," *id.* at 668-69, "a

has established a prima facie case of an unlawful restraint, rebuttable by defendants' showing of a legitimate justification for the agreement. *Cf. NCAA*, 468 U.S. at 110 (an agreement effecting a "naked restraint on price and output requires some competitive justification"). Although patent settlements are not properly viewed as naked restraints, money plainly can be used to buy market exclusion, so that payments appearing to be in exchange for market exclusion similarly require justification. Evidence of legitimate justification, if any exists, is likely to be in the hands of the antitrust defendants, whose burden it should therefore be to produce it once plaintiffs establish their prima facie case.

2. It is neither necessary nor appropriate to determine whether the patent holder would likely have prevailed in the patent infringement litigation in determining liability for a Hatch-Waxman reverse payment settlement under the rule of reason.[11] To be sure, settlements might

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presumption that the side deal provides disguised payment to the generic firm" for delayed entry is justified, *id.* at 669.

[11]The determination would be based on information available to the parties when they entered into the settlement. *See Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003) ("[T]he reasonableness of agreements under the antitrust laws [is] to be judged at the time the agreements are entered into."); *Tamoxifen*, 466 F.3d at

provide for more competition than would prevail if the patent were ultimately found to be valid and infringed. That possibility might preclude a purchaser's damage claim in some circumstances, *see Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 342 (1990), but it is not a sufficient reason for making the liability standard turn on proof of what would have happened had the parties not settled.

Liability properly turns on whether, in avoiding the risks that accompany infringement litigation, the parties have by contract obtained more exclusion than warranted in light of those risks. Basing litigation on this principle should approximate the balance struck in the Patent Act over the entire class of agreements of this kind.

Moreover, practical considerations support this approach. Requiring a court to determine whether the patentee would have prevailed – to base antitrust liability on a binary determination of patent validity and infringement vel non – would unduly complicate the litigation by

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228 (Pooler, J., dissenting) ("I would rely primarily on the strength of the patent as it appeared at the time at which the parties settled"). There is no reason to suspect in cases like this that changes in market conditions will make a previously reasonable agreement unreasonable.

requiring at least a mini-trial of the patent issue in the antitrust case,[12] and likely more. Such a requirement could reduce parties' incentives to settle the patent litigation, despite the strong public policy favoring settlements. And embedding a patent trial within the antitrust trial would align the infringement defendant with the infringement plaintiff in the antitrust case, reducing the accuracy of any determination.

If the settlement involves a payment in exchange for the generic manufacturer's agreement to withdraw its challenge to the patent and to delay entry, there is no need to determine whether the patent would in fact have been held invalid or not infringed in order to conclude that the settlement likely disadvantaged consumers. Without the payment, the settlement would likely have allowed earlier entry, or the litigation would have continued, with the possibility that the generic firm would win. The payment reveals the patent owner's lack of certainty about its litigation prospects and its desire to avoid the risk of a competition-

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[12]We have suggested elsewhere that a court could conduct a limited evaluation of the claims in the settled patent litigation rather than conduct a full trial of those claims, Brief for the United States as Amicus Curiae at 13, *Joblove v. Barr Labs., Inc.*, *cert. denied*, 551 U.S. 1144 (2007) (No. 06-830), but as part of a rule of reason analysis, not as a single decisive determination, *id.* at 12-13.

creating loss. Thus, as the Federal Trade Commission concluded, "the possible existence of a so-called 'reverse payment' raises a red flag that . . . mandates a further inquiry." FTC Decision at 991.

D. Defendants Are Entitled To Rebut The Presumption By Offering Evidence That The Reverse Payment Did Not Purchase Reduced Competition

If the plaintiff makes a prima facie showing that a reverse payment purchased reduced competition, the burden shifts to the defendants in a rule-of-reason analysis that "focuses directly on the challenged restraint's impact on competitive conditions."[13] *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 688 (1978). The defendants, therefore, must focus on a comparison between competition under the settlement and what they expected had the patent infringement suit been litigated to judgment. Neither precision nor certainty should be required; the defendants' burden is only to show that the overall terms of the settlement did not "impose[ ] an unreasonable restraint on

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[13]The defendants might negate the prima facie case, rather than rebut the presumption that flows from it. If the settlement was part of a larger arrangement, the defendants might show that the payment was reasonable consideration for some legitimate concession, e.g., backup manufacturing services.

competition," *State Oil*, 522 U.S. at 10, in view of their contemporaneous evaluations of the likelihood of an invalidity or noninfringement judgment.[14]

1. The defendants clearly rebut the presumption if they show the payment was no more than an amount commensurate with the patent holder's avoided litigation costs. A payment up to the amount saved by avoiding litigation does not suggest the settlement departs from the expected outcome of litigation. *See* FTC Decision at 1000 n.69.

The defendants should have considerable leeway in comparing the payment to avoided litigation costs. The relevant cost measure includes costs of business disruption, potentially substantial yet difficult to measure. Moreover, a modest reverse payment to "bridge the gap" between parties with different expectations about litigation outcomes

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[14] *See, e.g.*, Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, J. Econ. Perspectives, Spring 2005, at 75, 93 n.19 (evidence of risk aversion, imperfect capital markets, or asymmetric information can overcome the presumption); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1759-60 (2003) (presumption can be rebutted by "showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit").

may be a legitimate cost of settlement. *See* FTC Decision at 1002. In any event, payments not greatly in excess of avoided litigation costs are unlikely to impair competition significantly.

2. If a payment is greatly in excess of avoided litigation costs, the rule of reason inquiry focuses on the competitive implications of other terms in the settlement, in particular on the nature and extent of the generic competition permitted. The defendants will be unable to carry their burden if the settlement allowed no generic competition until patent expiration. That is so even if the parties ex ante believed that the patentee would have a greater than 50% likelihood of prevailing if the case were litigated to its conclusion. Even in that situation, a settlement of this nature is anticompetitive because it eliminates the *possibility* of competition from the generic prior to the expiration of the patent. *See supra* p. 15. If all such cases were litigated to judgment, some presumably would culminate in rulings for the generic manufacturers, thereby increasing generic competition in the aggregate. Moreover, a rule precluding this type of settlement would enhance competition by encouraging (though not compelling) the parties to negotiate alternative settlements that did not include substantial

reverse payments but rather provided for earlier entry by the generics. *See supra* pp.22-23 & note 9.

If the settlement provides for generic entry before the expiration of the patent, the defendants can carry their burden by showing that the settlement preserved a degree of competition reasonably consistent with what had been expected if the infringement litigation went to judgment. In other words, defendants can overcome the presumption by showing that avoiding the Patent Act's procedures for excluding alleged infringers did not depart from the balance struck in the Patent Act.

The defendants' burden is to show that, despite the reverse payment, the agreed-upon entry date and other terms of entry reasonably reflected their contemporaneous evaluations of the likelihood that a judgment in the patent litigation would have resulted in generic competition before patent expiration.[15] The defendants cannot carry their burden simply by showing that they thought that the patent holder would very likely win

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[15]Post-settlement evidence, as from subsequent litigation, has little probative value. Accordingly, mini-trials of validity and infringement issues are unlikely to be productive and unlikely to occur in determining whether competition was unreasonably restrained. We express no view on the showing required to support a purchaser's damage claim. *See supra* pp. 25-26.

the litigation. However high the parties thought that likelihood, a reverse payment settlement permitting significantly less generic competition than would be consistent with that likelihood would be an unreasonable restraint on competition. Similarly, the defendants cannot carry their burden simply by showing that the settlement allowed significant generic competition before patent expiration – significantly more competition than the agreement provides may be consistent with the parties' contemporaneous evaluations of the likelihood the patent holder would be successful.

As previously noted, precision is impossible in comparing the state of competition under the settlement to that consistent with the parties' contemporaneous evaluations concerning the outcome of the patent litigation.[16] The defendants can carry their burden by providing a

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[16]Patent litigation is uncertain. Moreover, competition under the settlement could entail entry by a single generic under a license with royalty payments, whereas competition after an invalidity judgment would be unencumbered and could involve multiple generic entrants after the 180-day exclusivity period. (Competition after a judgment of noninfringement would also be unencumbered and could in some cases also involve multiple generic entrants.) Comparing these two worlds presents difficulties such as the possibility that high royalties limit the force of generic competition.

reasonable explanation that the payment bought something other than an additional limitation of competition, so that there is no reason to find that the settlement does not provide a degree of competition reasonably consistent with their contemporaneous evaluations.

CONCLUSION

The Court should vacate the judgment and remand for further proceedings.

Respectfully submitted.

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CERTIFICATE OF BAR MEMBERSHIP

Because this brief is filed on behalf of the United States, we understand that membership in this Court's bar is not required.

/s/ David Seidman
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May 18, 2011

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1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 6,554 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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CERTIFICATE OF SERVICE

I, David Seidman, hereby certify that on May 18, 2011, I electronically filed the foregoing Brief for the United States as Amicus Curiae Supporting Plaintiffs-Appellants with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the CM/ECF system. Attorneys for each party in the case who are registered CM/ECF users will be served by the CM/ECF system.

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