05-2851-cv(L)

05-2852-cv (CON), 05-2863-cv (CON)*

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

Arkansas Carpenters Health and Welfare Fund, Maria Locurto,
Paper, Allied-Indus, United Food and Commercial Workers Union-Employer,
Louisiana Wholesale Drug Co., Inc., CVS Pharmacy, Inc., Rite Aid Corporation,
Arthur's Drug Store, Inc.,

Plaintiffs-Appellants,

Sol Lubin, Ann Stuart, Linda K. McIntyre,

Plaintiffs,

v.

Bayer, AG, Bayer Corp., formerly doing business as Miles Inc.,
Hoechst Marion Roussel, Inc., The Rugby Group, Inc.,
Watson Pharmaceuticals, Inc., Barr Laboratories, Inc.,

Defendants-Appellees.

On Appeal from the United States District Court
for the Eastern District of New York

BRIEF FOR THE UNITED STATES IN RESPONSE TO THE COURT'S INVITATION

Christine A. Varney
Assistant Attorney General

Philip J. Weiser
Deputy Assistant Attorney General

Catherine G. O'Sullivan
David Seidman
Attorneys
U.S. Department of Justice
950 Pennsylvania Ave. NW, Room 3224
Washington, DC 20530
(202)-514-4510

* 05-2863-cv has been transferred to the Federal Circuit Court of Appeals. *See* Order filed 11/7/07.

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STATEMENT OF INTEREST AND QUESTION PRESENTED

This brief is submitted in response to the Court's letter of April 6, 2009, inviting the Executive Branch to address "whether settlement of patent infringement lawsuits violates the federal antitrust laws when a potential generic drug manufacturer withdraws its challenge to the patent's validity, which if successful would allow it to market a generic version of a drug, and the brand-name patent holder, in return, offers the generic manufacturer substantial payments." We also address the question presented in the Court's letter of April 28, 2009: whether the "Court has jurisdiction over these appeals where the probability of invalidity of the ciprofloxacin hydrochloride patent may be an issue."

STATEMENT

1. The questions the Court invited the United States to address arise 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 at scattered sections of titles 21 and 35 of the United States Code); *see In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 190-93 (2d Cir. 2006) ("*Tamoxifen*") (summarizing "Regulatory Background"). 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 must list with 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). 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, 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 it makes the filing of a paragraph-IV certification an act of patent infringement. 35 U.S.C. 271(e)(1)-(2). It also requires the ANDA applicant to notify the patent owner and NDA applicant of this patent challenge. 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 the branded drug manufacturer to file its infringement suit within 45 days of notification of a paragraph-IV certification, by providing that such a suit 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 filing of an ANDA 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. The introduction of a generic drug is an event with unique and dramatic economic consequences because generics are significantly lower-priced bioequivalents of branded drugs, with substitution spurred

by state "generic substitution laws." In *Tamoxifen*, this Court discussed the practical consequences of generic drug economics, noting strong incentives for the manufacturer of the branded drug to pay a paragraph-IV ANDA filer to settle the patent infringement litigation (that is, to make a "reverse 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 Tamoxifen*, 466 F.3d at 207, 209.[1] Moreover, because it is unlikely to recover damages, the branded firm has little to gain from a litigated judgment in its favor if it can protect the lucrative status quo by settlement. And, although an unfavorable judgment as to patent validity will prevent the branded firm from excluding any future challenger, 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, by contrast, will lose

[1]Similar, if not identical, issues arise regarding patent infringement rather than invalidity of the patent. The Court's question, however, focused on challenges to patent validity.

little – principally, the costs of litigating the validity of the patent – 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.2d at 206-07. If it gets a judgment in its favor, the first ANDA filer may market its drug and has 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). But that may not be the generic firm's most favorable outcome.

Significantly, as this Court observed in *Tamoxifen*, if the patent is found invalid, "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." *Id.* at 209. It is therefore likely to be in the patent holder's economic interest "to pay some portion of that difference to the generic manufacturer to maintain the patent-monopoly market for itself." And it is likely to be in the economic interest of the generic manufacturer "to accept such a payment if it is offered" and agree to end its patent challenge and not to compete for some or all of the remaining life of the patent, because the payment may be larger than the generic drug firm's

expected gain from litigating the validity issue. *Id.* Indeed, the patent holder might be willing to pay more than the generic firm would stand to gain 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, this Court 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. The United States described this standard as "incorrect," Brief for the United States as Amicus Curiae, at 1, *Joblove v. Barr Labs., Inc.*, S. Ct. No. 06-830 (2007) ("U.S. *Joblove* Br."), primarily because it does not take into account "the strength of the infringement claim beyond a determination that the claim was not objectively baseless." *Id.* at 13-14.

3. In this case, appellee-defendant Barr, a generic drug manufacturer, filed an ANDA with a paragraph-IV certification, seeking

authority to market a generic version of appellee-defendant Bayer's branded drug ciprofloxacin hydrochloride ("Cipro").[2] Bayer filed a patent infringement suit against Barr within the 45-day period. The suit was settled on terms that provided for a relatively small initial reverse payment. The settlement agreement also gave Bayer the choice of supplying Barr with Cipro for distribution under Barr's brand years before the Cipro patent expired or making substantial additional reverse payments to keep Barr from entering the market. JA 8477-79. Bayer opted to make the payments and thus kept Barr off the market until six months before patent expiration, when Barr began selling a product supplied by Bayer under a licence with an 85% royalty. JA 8478-79, 8488, 8524.

A number of Cipro purchasers filed suit against Bayer and Barr (and other defendants), alleging that this settlement violated Section 1 of the Sherman Act, 15 U.S.C. 1, by suppressing market entry of generic Cipro, JA 1707. In consolidated proceedings, the district court in 2003 held that the existence of a Section 1 violation should be determined

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[2]We refer to the Bayer defendants-appellees collectively as "Bayer" and the other defendants-appellees collectively as "Barr."

pursuant to the rule of reason, rather than the per se rule. JA 1769-71, 1814-15. In 2005, the court granted defendants' motion for summary judgment, holding that it would be inappropriate for the court to "conduct an after-the-fact inquiry into the validity of the underlying patent," JA 8506, or "to engage in an after-the-fact analysis of the patent's likely validity [or] to discount the exclusionary power of the patent by any probability that the patent would have been found invalid." JA 8528. Separate groups of plaintiffs filed three appeals in this Court.

4. On November 7, 2007, this Court, ruling on a motion to transfer the three appeals from the decision below, ordered number 05-2863-cv transferred to the Federal Circuit, "because the *Walker Process* claim in that case arises out of patent law." JA 8606. The Court denied the motion as to the other two appeals "because the claims therein rely on several theories, including alternative theories that do not require the determination of any substantial question of patent law." *Id.*

SUMMARY OF ARGUMENT

The United States takes no position on the ultimate merits of this appeal. Nor do we offer a comprehensive antitrust analysis of patent settlement agreements. We focus on the narrow questions the Court posed with respect to settlements involving a payment from the patent holder to the alleged infringer in return for withdrawal of a validity challenge in the context of the Hatch-Waxman Act.

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 of patent invalidation in exercising it. 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. The anticompetitive potential of reverse payments in the Hatch-Waxman context 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.

Whether this Court properly has jurisdiction over these appeals depends on the elements of a plaintiff's claim. A well-pleaded complaint requires no allegation regarding a question of patent law. Thus, in our view, this Court has jurisdiction over these appeals.

ARGUMENT

I. "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 SECTION 1 OF 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. 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 filing 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.[3] As the district court explained, "legitimate government petitioning, including the filing of a non-sham lawsuit, is immune from attack under the Sherman Act." JA 1732 (citing *E. R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965)). *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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[3] "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). 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. *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, 147 (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 risk that enforcement litigation will lead to invalidation of the patent by settling infringement claims prior to judgment. As a general matter, settlement of patent disputes, like

voluntary resolution of other litigation, 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 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"); JA 1732-33 ("defendants' conduct pursuant to the agreements in this case is not afforded immunity from the antitrust laws under the *Noerr-Pennington* doctrine"). The Patent Act thus offers the patentee a choice between exercising its statutory privilege to protect its interests through litigation to enforce the patent – with the attendant risk that the patent may be invalidated – and relying on private measures that avoid the risk of patent invalidation but provide no antitrust immunity.

3. This Court's *Tamoxifen* standard inappropriately permits patent holders to contract their way out of the statutorily imposed risk that patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract. Except in instances of

knowing fraud or objectively baseless patent claims, the *Tamoxifen* standard treats a private settlement agreement excluding competition as the equivalent of a litigated judgment affirming the validity of the patent. In most cases, this standard effectively bars considering whether the agreement might violate the antitrust laws, and so offers no protection to the public interest in eliminating undeserved patents. The *Tamoxifen* standard thus upsets the carefully crafted balance that Congress struck in the Patent Act. *See, e.g., Edward Katzinger Co. v. Chicago 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 *Tamoxifen* 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 of invalidation through litigation. 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) (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 contracts as if they were litigated injunctions, while evading the risk of patent invalidation, deprives consumers of significant benefits

from price competition in the pharmaceutical industry.[4]

This Court has recognized the problem, acknowledging in *Tamoxifen* 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." 466 F.3d at 211. However, relying on the district court's decision in this case, JA 8514, the Court 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 FTC v. Cephalon, Inc.*, 551 F. Supp. 2d 21, 22 (D.D.C. 2008) (granting transfer motion) (drug manufacturer settled with four generic firms, which agreed to delay market entry "in return for lucrative side agreements"). This discounting ignores important aspects of the Hatch-Waxman context. The Act provides only a first paragraph-IV ANDA

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[4]To simplify exposition, we assume throughout that the patented drug at issue lacks substantial competition from other, non-infringing, 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. *Illinois Tool Works Inc. v. Independent Ink, Inc.*, 547 U.S. 28 (2006).

filer the incentive of a 180-day exclusivity period. And even if subsequent ANDA applicants were not blocked by the exclusivity, 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. Nor did the Court give weight to the possibility that the first paragraph-IV ANDA filer could be uniquely positioned to challenge the validity of the patent. 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. The statutory presumption of patent validity, 35 U.S.C. 282, provides no warrant for the *Tamoxifen* approach.[5] It,"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 the validity of an issued patent, *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985). Moreover, the presumption of patent validity is rebuttable. There is no

[5]Still less does it provide a warrant for that approach when infringement is disputed, since there is no statutory presumption of infringement.

basis for a standard that treats the presumption of validity as virtually conclusive and allows it to serve as a substantive basis to limit the application of the Sherman Act – particularly since many litigated patents, notably in the Hatch-Waxman Act context, are held invalid. *See* pp. 15-16, *supra*. 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.

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 Georgia, Inc.*, 498 U.S. 46 (1990) (per curiam); 12 Herbert Hovenkamp, Antitrust Law ¶ 2030b, at 213 (2d ed. 2005) ("the 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 agreements settling patent infringement litigation 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. Board 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 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, 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 patent being invalidated (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.[6]

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[6]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

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 challenge to the patent 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 challenge to the patent's validity; 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 the validity challenge,[7] it has established a prima facie case. *Cf. NCAA*, 468 U.S. at 110 ("naked restraint on price and output requires some competitive justification even in the absence of a detailed market analysis").

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unknown in the settlement of other patent litigation.

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

2. A patent holder can use a payment to obtain exclusion of the generic drug firm from the market. This case illustrates the point with unusual clarity. As part of the settlement, Bayer paid Barr $49.1 million for Barr to abandon its paragraph-IV certification. In addition, Barr agreed not to manufacture Cipro for distribution in the United States, while Bayer agreed either to supply Barr with Bayer-manufactured Cipro for distribution or to make quarterly payments to Barr for six years; Bayer chose to make the payments, which eventually totaled roughly $349 million. JA 8477-79. The exchange of money for continued market exclusivity is starkly apparent.

3. 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.[8] To be sure, settlements might

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[8]The determination would be based on information available to the parties when they entered into the settlement. *See Valley Drug Co. v. Geneva Pharms., 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 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

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 whether the patent would have been found invalid.

Liability properly turns on whether, in avoiding the prospect of invalidation that accompanies infringement litigation, the parties have by contract obtained more exclusion than warranted in light of that prospect. 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 invalidity vel non – would unduly complicate the litigation by

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conditions will make a previously reasonable agreement unreasonable.

requiring at least a mini-trial of the patent issue in the antitrust case,[9] 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 validity 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 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 of an invalidity determination. The payment reveals the patent owner's lack of certainty about validity and

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[9]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, U.S. *Joblove* Br. at 13, but as part of a rule of reason analysis, not as a single decisive determination, *id.* at 12-13. We acknowledge some tension between statements in our *Joblove* brief and our current views.

its desire to avoid the risk of an invalidity determination. Thus, as the Federal Trade Commission concluded in *In the Matter of Schering-Plough Corp.*, 136 F.T.C. 956, 991 (2003) ("FTC Decision"), *vacated*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), "the possible existence of a so-called 'reverse payment' raises a red flag that . . . mandates a further inquiry."[10]

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."[11] *Nat'l Soc'y of Prof'l*

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[10]In *Schering-Plough*, the defendants contended that the payment was not for exclusion of the generic from the market, but rather for a license to a different drug. The FTC determined otherwise, FTC Decision at 1051, but the court of appeals rejected that determination, *Schering-Plough*, 402 F.3d at 1070-71.

[11]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.

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 with 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 competition," *State Oil*, 522 U.S. at 10, in view of their contemporaneous evaluations of the likelihood of an invalidity judgment.[12]

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

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[12] *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) (Professor Shapiro currently is a U.S. Department of Justice official); 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) the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit").

avoiding litigation does not suggest the settlement departs from the expected outcome of litigation. *See* FTC Decision at 979 n.37.

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 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* pp. 13-14, 22, *supra*. 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* pp. 21-22 & n.6, *supra*.

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.[13] The defendants cannot carry their burden simply by showing that they thought that the patent's validity very likely would be upheld. However high the parties thought the likelihood the patent would be upheld, 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 would be upheld.

As previously noted, precision is impossible in comparing the state of competition under the settlement to that consistent with the parties'

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[13]Post-settlement evidence, as from subsequent litigation, has little probative value. Accordingly, mini-trials of patent validity 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* pp. 24-26, *supra*.

contemporaneous evaluations concerning the outcome of the patent litigation.[14] The defendants can carry their burden by providing a 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.

II. THIS COURT HAS JURISDICTION OVER THESE APPEALS

The Federal Circuit, rather than this Court, would have jurisdiction over appeals from a district court in a private antitrust case only if the jurisdiction of the district court were "based, in whole or in part, on [28 U.S.C. 1338]." 28 U.S.C. 1295(a)(1). A district court's jurisdiction is based on section 1338 if the civil action arose "under any Act of Congress relating to patents." 28 U.S.C. 1338(a).

A case arises under patent law if "a well-pleaded complaint

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[14]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. Comparing these two worlds presents difficulties such as the possibility that high royalties limit the force of generic competition.

establishes either that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809 (1988). Patent law does not create the antitrust causes of action at issue here, so the existence of Federal Circuit jurisdiction depends on whether patent law is a necessary element of one of the well-pleaded claims.

As the Court phrased its question to the government ("where the probability of invalidity of the . . . patent may be an issue"), patent law would not be a necessary element of one of the well-pleaded claims. First, "may be an issue" implies that the probability of invalidity would not be a necessary element of one of the well-pleaded complaints. Second, the Federal Circuit would not have jurisdiction if that probability was an issue because it was raised as a defense, rather than as an element of a claim (even if anticipated in the complaint). *See Christianson*, 486 U.S. at 809 (noting that a patent law defense does not mean a case arises under patent law even if that defense is the only question truly at issue). Third, it is not clear that determining the

probability of invalidity necessarily raises an issue of patent law. It may involve only determining the reasonably perceived likelihood, as of the time of settlement, that a court would hold a patent invalid.

As for the instant appeals, this Court has already determined that the claims "rely on several theories, including alternative theories that do not require the determination of any substantial question of federal law," and that therefore jurisdiction does not lie under 28 U.S.C. 1338. Order of Nov. 7, 2007, at 2, JA 8606. We have no occasion to question that determination.

A claim susceptible of analysis under the rule of reason approach we recommended here would not lead to Federal Circuit jurisdiction. Neither allegation nor proof of the elements of the claim requires any reliance on patent law or any assertion regarding the probability of patent invalidity. A court's determination of the claim does not require a determination of the probability of patent invalidity – unless the defendant, by way of defense, answers that, despite a reverse payment, the settlement is consistent with the likelihood that the patent would be found valid. To be sure, defendants may argue that patent law permits a patent holder to purchase exclusion for cash in settling patent

litigation (and thus the purchase cannot be unlawful under the antitrust laws), and that whether it does presents a substantial question of patent law. Assuming, arguendo, that to be a *substantial* question of patent law rather than mere wishful thinking, it nevertheless is a defense, which does not produce Federal Circuit jurisdiction over an appeal.

CONCLUSION

The answer to the Court's first question is that a settlement involving a payment to the alleged drug patent infringer in exchange for its agreement to withdraw its challenge to the patent and delay bringing its generic drug to market is presumptively unlawful and requires the defendant to offer justifications in order to avoid antitrust liability. The answer to the Court's second question is that the

possibility that the probability a patent is invalid will be an issue in an appeal does not give the Federal Circuit jurisdiction over that appeal.

Respectfully submitted.

Christine A. Varney
Assistant Attorney General

Philip J. Weiser
Deputy Assistant Attorney General

Catherine G. O'Sullivan
David Seidman
Attorneys
U.S. Department of Justice
950 Pennsylvania Ave. NW, Room 3224
Washington, DC 20530
(202)-514-4510

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1. This brief complies with the type-volume limitation of Fed. R. App. P. 29(d) and 32(a)(7)(B) because it contains 6928 words excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in 14-point Universe, a proportionally-spaced TrueType font, using WordPerfect Version 10.

Dated: July 6, 2009

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David Seidman

ANTI-VIRUS CERTIFICATION FORM

See Second Circuit Interim Local Rule 25(a)6.

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David E. Everson
Victoria L. Smith
Stinson Morrison Hecker LLP
1201 Walnut St., Ste. 2900
Kansas City, MO 64106-2150

Heather S. Woodson
Stinson Morrison Hecker LLP
10975 Benson, Ste. 550
12 Corporate Woods
Overland Park, KS 66210

Counsel for Appellees Hoechst Marion Roussel, Inc., The Rugby Group, Inc. and Watson Pharmaceuticals, Inc.

Karen N. Walker
Edwin U
Gregory L. Skidmore
Kirkland & Ellis LLP
655 15th St., N.W., Ste. 1200
Washington, DC 20005

Counsel for Appellee Barr Laboratories, Inc.

Fred H. Bartlit
Peter B. Bensinger, Jr.
Michael J. Valaik
Paul J. Skiermont
Bartlit Beck Herman Palenchar & Scott LLP
54 West Hubbard St., Ste. 300
Chicago, IL 60654

Phillip A. Proger
Lawrence Rosenberg
JONES DAY
51 Louisiana Avenue, N.W.
Washington, DC 20001
202-879-4668 (tel.)
202-626-1700 (fax)

Counsel for Appellees Bayer AG and Bayer Corporation

Bruce E. Gerstein
Barry S. Taus
Garwin Gerstein & Fisher, LLP
1501 Broadway, Ste. 1416
New York, NY 10036

David F. Sorensen
Berger & Montague, P.C.
1622 Locust St.
Philadelphia, PA 19103
Counsel for Appellant Louisiana Wholesale Drug Co., Inc.

Don L. Bell, II
National Association of Chain Drug Stores
413 North Lee St.
P.O. Box 1417-D49
Alexandria, VA 22313
Counsel for Amicus Curiae National Association of Chain Drug Stores

Steve D. Shadowen
Monica L. Rebuck
Hangley Aronchick Segal & Pudlin
30 North Third St., Ste. 700
Harrisburg, PA 17101
Counsel for Appellants CVS Pharmacy, Inc. and Rite Aid Corporation

Paul E. Slater
Sperling & Slater, P.C.
55 W. Monroe St.
Chicago, IL 60603
Counsel for Amicus Curiae American Antitrust Institute

Stacey J. Canan
Bruce B. Vignery
AARP Foundation
601 E. St., NW
Washington, D.C. 20049
Counsel for Amici Curiae AARP, Prescription Access Litigation and Public Patent Foundation

_____

David Seidman