United States Court of Appeals for the Federal Circuit

2008-1097

IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION

ARKANSAS CARPENTERS HEALTH AND WELFARE FUND, PAPER, A.F. OF L. - A.G.C. BUILDING TRADES WELFARE PLAN, MARK ASTON, BOARD OF TRUSTEES OF THE UNITED FOOD & COMMERCIAL WORKERS OF ARIZONA HEALTH AND WELFARE FUND, ADELE BRODY, MICHELLE CROSS, DONNA FRANCK, KRISTINE GADDIS, DAVID GREEN, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, JOHN H. IRONS, LOCAL 1199 NATIONAL BENEFIT FUND FOR HEALTH AND HUMAN SERVICES EMPLOYEES, MARIA LOCURTO, CAROLINE M. LOESCH, KIMBERLY MCCULLAR, LINDA K. MCINTYRE, MECHANICAL CONTRACTORS-UA LOCAL 119 WELFARE PLAN, THERESA MEYERS, PATRICIA NELSON, FRANCES NORRIS, PAPER, ALLIED-INDUSTRIAL, CHEMICAL AND ENERGY WORKERS INTERNATIONAL UNION, AFL-CIO, CLC, MARY ANN SCOTT, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, MAURICE STEWART, ANN STUART, UNITED FOOD & COMMERCIAL WORKERS AND PARTICIPATING FOOD INDUSTRY EMPLOYERS TRI-STATE HEALTH & WELFARE FUND, and VISTAHEALTHPLAN, INC.,

Plaintiffs-Appellants,

v.

BAYER AG and BAYER CORP.,

Defendants-Appellees,

and

HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC. (doing business as Rugby Laboratories, Inc.), and WATSON PHARMACEUTICALS, INC.,

Defendants-Appellees,

and

BARR LABORATORIES, INC.,

Defendant-Appellee.

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Appealed from: United States District Court for the Eastern District of New York

Senior Judge David G. Trager

United States Court of Appeals for the Federal Circuit

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HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC. (doing business as Rugby Laboratories, Inc.), and WATSON PHARMACEUTICALS, INC.,

Defendants-Appellees,

and

BARR LABORATORIES, INC.,

Defendant-Appellee.

Appeal from the United States District Court for the Eastern District of New York, in 1:00-MD-01383, Senior Judge David G. Trager.

DECIDED: October 15, 2008

Before SCHALL and PROST, Circuit Judges, and WARD, District Judge.[*]

PROST, Circuit Judge.

This case under the Hatch-Waxman Act presents the issue of whether a settlement agreement between a patent holder and a generic manufacturer violates the antitrust laws. The agreements here involve a reverse payment from the patent holder to the generic manufacturer, but do not implicate the 180-day exclusivity period. Indirect purchasers of Cipro and several advocacy groups ("appellants") appeal the grant of summary judgment of their federal antitrust claims and dismissal of their state antitrust claims against the patent holders and brand-name manufacturers, Bayer AG and Bayer Corp. (collectively "Bayer"), and the generic manufacturers, Barr Labs., Inc. ("Barr"), Hoechst Marion Roussel, Inc. ("HMR"), The Rugby Group, Inc. ("Rugby"), and Watson Pharmaceuticals, Inc. ("Watson") (collectively "generic defendants"). The United States District Court for the Eastern District of New York granted Bayer's and the generic defendants' motion for summary judgment, holding that any anti-competitive effects caused by the settlement agreements between Bayer and the generic defendants were within the exclusionary zone of the patent, and thus could not be redressed by federal antitrust law. In re Ciprofloxacin Hydrochloride Antitrust Litigation,

[*] Honorable T. John Ward, District Judge, United States District Court for the Eastern District of Texas, sitting by designation.

363 F. Supp. 2d 514 (E.D.N.Y. 2005) ("Cipro II"). The court further granted Bayer's motion to dismiss the state antitrust claims. For the reasons set forth below, we affirm.

I

A

Bayer is the owner of U.S. Patent No. 4,670,444 ("the '444 patent"). The patent relates to certain quinoline- and napthyridine-carboxylic acid compounds with antibacterial properties and methods of administering the compounds to combat bacterial illnesses. '444 patent, col.1 ll.13-17, col.2 ll.28-32, claims 1, 21. More particularly, the patent is directed to ciprofloxacin hydrochloride, the compound that is the active ingredient in Cipro® ("Cipro"). Id., claim 12. The patent issued on June 2, 1987, and Bayer's predecessor obtained approval from the Food and Drug Administration ("FDA") to market Cipro in October 1987. The FDA granted Bayer an additional six-month period of marketing exclusivity (pediatric exclusivity) following the expiration of the patent on December 9, 2003.

In October 1991, Barr filed an abbreviated new drug application ("ANDA") for a generic version of Cipro. The ANDA included a Paragraph IV certification[1] indicating that Barr sought to market its generic drug before expiration of the '444 patent on the grounds that the patent was invalid and unenforceable.[2] Specifically, Barr asserted that the patent was invalid based on obviousness under 35 U.S.C. § 103 and obviousness type double patenting under 35 U.S.C. § 101, and unenforceable due to inequitable

[1] The filer of a Paragraph IV ANDA certifies that the patent is invalid or will not be infringed by the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[2] Barr did not certify that its product did not infringe the '444 patent.

conduct. Under the Hatch-Waxman Act, the first filer of a Paragraph IV ANDA is automatically entitled to a 180-day period of market exclusivity, which, in the version of the Act in effect at the time, begins to run either on the date that the first ANDA filer begins to market its drug or on the date of a final court decision finding the patent to be invalid or not infringed, whichever is earlier. 21 U.S.C. § 355(j)(4)(B)(iv) (1988). Thus, as the first Paragraph IV ANDA filer, Barr was entitled to the 180-day exclusivity period.

On January 16, 1992, Bayer sued Barr for patent infringement in the Southern District of New York. Barr answered and counterclaimed for a declaratory judgment that the '444 patent is invalid and unenforceable and that its generic ciprofloxacin would not infringe the '444 patent. In 1996, Rugby (a subsidiary of HMR) and Barr entered into the "Litigation Funding Agreement," in which Rugby agreed to help Barr fund its litigation against Bayer in exchange for half of any profits realized from Barr's sale of ciprofloxacin. Also, in 1996, Bayer entered into settlement discussions with HMR and Barr.

Just before trial, Bayer, Barr, HMR, and Rugby entered into the following agreements (collectively "the Agreements"): (1) the "Barr Settlement Agreement" between Bayer and Barr; (2) the "HMR/Rugby Settlement Agreement" among Bayer, HMR, and Rugby; (3) the "Apotex Settlement Agreement" among Bayer, Bernard Sherman (Barr's principal shareholder), and Apotex (another company controlled by

Sherman); and (4) the "Cipro Supply Agreement" among Bayer, Barr, and HMR.[3]

The first three agreements provided that Barr, HMR, Rugby, Apotex, and Bernard Sherman would not challenge the validity or enforceability of the '444 patent. Pursuant to the Barr Settlement Agreement, Barr agreed to convert its Paragraph IV ANDA to a Paragraph III ANDA, thus certifying that it would not market its generic version of Cipro until after the '444 patent expired.[4] See 21 U.S.C. § 355(j)(2)(A)(vii)(III). In exchange, Bayer agreed to make a settlement payment to Barr of $49.1 million.

Under the Cipro Supply Agreement, Bayer agreed to either supply Barr with Cipro for resale or make quarterly payments (referred to as "reverse payments" or "exclusion payments") to Barr until December 31, 2003.[5] In return, Barr agreed not to manufacture, or have manufactured, a generic version of Cipro in the United States. Beginning at least six months before the '444 patent expired, Bayer agreed to allow Barr to sell a competing ciprofloxacin product. Bayer and Barr then entered into a consent judgment, whereby Barr affirmed the validity and enforceability of the '444 patent and admitted infringement.

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[3] Notably, the Agreements were entered into before the 2003 amendments to the Hatch-Waxman Act, requiring a patent holder and a first Paragraph IV ANDA filer who settle their patent litigation to file their agreement with the Federal Trade Commission and Department of Justice for review, and if the agreement is found to violate the antitrust laws, the first ANDA filer loses its right to the 180-day exclusivity period. Pub. L. No. 108-173, § 1112; see 21 U.S.C. § 355(j)(5)(D)(i)(V).

[4] Barr, however, preserved the option to reamend its ANDA to a Paragraph IV certification—in order to reclaim the 180-day exclusivity period—in the event a court declared the '444 patent to be invalid or unenforceable.

[5] Added to the $49.1 million initial payment, the payments from Bayer to Barr totaled $398.1 million. Barr shared the payments equally with HMR.

On July 25, 1997, Bayer filed for reexamination. Bayer cancelled and amended certain claims, and the validity of the remaining claims of the '444 patent was reaffirmed by the Patent and Trademark Office ("PTO") in the reexamination certificate. In particular, the patentability of claim 12, directed to ciprofloxacin hydrochloride, was confirmed.

Thereafter, four other companies—Ranbaxy, Mylan, Schein, and Carlsbad—filed Paragraph IV ANDAs for a generic version of Cipro. Bayer sued each of them for infringement of the reexamined '444 patent. The issue of inequitable conduct was not adjudicated in any of the actions. Bayer defeated Schein and Mylan's challenges to the validity of the '444 patent on summary judgment. Bayer AG v. Schein Pharm., Inc., 129 F. Supp. 2d 705 (D.N.J. 2001), aff'd, 301 F.3d 1306 (Fed. Cir. 2002). The validity of the '444 patent was upheld after a bench trial in the Carlsbad case. Bayer AG v. Carlsbad Tech., Inc., No. 01CV0867-B (S.D. Cal. June 7, 2002 & Aug. 7, 2002). The Ranbaxy case was dismissed after Ranbaxy withdrew its Paragraph IV certification.

B

In 2000 and 2001, direct and indirect purchasers of Cipro and advocacy groups filed several antitrust actions in federal courts challenging the Agreements. The cases were consolidated in the Eastern District of New York pursuant to 28 U.S.C. § 1407. In re Ciprofloxacin Hydrochloride Antitrust Litig., No. 1383, 2001 WL 253240 (J.P.M.L. Jan. 10, 2001). Thereafter, the plaintiffs filed a consolidated complaint containing Counts I-IV, which alleged that the Agreements constituted an illegal market allocation in violation of the prohibition on contracts in restraint of trade contained in sections 1 and 2 of the Sherman Act and in violation of various state antitrust and consumer protection laws.

On May 20, 2003, the district court denied the plaintiffs' motion for partial summary judgment that the Agreements were per se unlawful under the Sherman Act and under the state antitrust and consumer protection laws. In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188 (E.D.N.Y. 2003) ("Cipro I").

The plaintiffs then amended their complaint to add Count V, a state law Walker Process type[6] antitrust claim, alleging that Bayer unlawfully monopolized the ciprofloxacin market in violation of state antitrust laws by enforcing a patent obtained by fraud. Specifically, they alleged that Bayer violated state antitrust and/or consumer protection laws through fraud on the PTO and sham litigation in enforcing the '444 patent against Barr.

The parties filed cross-motions for summary judgment regarding whether the Agreements had anti-competitive effects under section 1 of the Sherman Act. The district court denied the plaintiffs' motion and granted Bayer's and the generic defendants' motion. Cipro II, 363 F. Supp. 2d at 548. Employing a rule of reason analysis, the district court first determined that the relevant market is ciprofloxacin and that Bayer had market power within that market. Id. at 520-23. The court then determined that any adverse effects on competition stemming from the Agreements were within the exclusionary zone of the '444 patent, and hence could not be redressed by antitrust law. Id. at 523-40. In so concluding, the court considered recent decisions by the Second Circuit, as well as other regional circuits, and rejected the plaintiffs'

[6] In Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172 (1965), the Supreme Court held that the enforcement of a patent procured by fraud on the patent office may be a violation of the Sherman Act provided that the other elements necessary to a Sherman Act claim are present. Id. at 177. Here, however, the plaintiffs alleged a violation of state antitrust laws.

argument that the exclusionary power of the patent, for the purpose of the anti-competitive effects analysis, should be tempered by the patent's potential invalidity. Id. Given the absence of evidence that the Agreements created a bottleneck on challenges to the '444 patent or otherwise restrained competition beyond the scope of the patent, the court concluded that the plaintiffs had failed to show that the Agreements had any anti-competitive effects on the market for ciprofloxacin beyond that permitted under the patent. Id. at 540. Thus, the court found it unnecessary to address the second and third steps of the rule of reason analysis. Id. at 541.

Bayer also filed a motion to dismiss Count V as preempted by federal patent law and barred by the statute of limitations. The district court agreed that Count V is preempted by federal patent law because the plaintiffs alleged no theory for a Walker Process claim or sham litigation claim that does not depend on a showing of misconduct before the PTO. Id. at 542-46. The court noted that Count V does not allege any misconduct other than misconduct before the PTO, i.e., there is no allegation of marketplace misconduct. Id. Thus, the court concluded that Count V rests entirely on patent law.[7] Id. The court also reasoned that Bayer's success in its litigation against Schein, Mylan and Carlsbad foreclosed any argument that its lawsuits were shams. Id. at 547. Because the court granted Bayer's motion to dismiss on preemption grounds, it did not reach whether Count V was barred by the statute of limitations. Id. at 547-48.

This appeal followed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).[8]

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[7] The court further noted that there was a serious question whether the indirect purchasers even had standing to assert a Walker Process claim. Id. at 547.

[8] Count V is subject to exclusive federal court jurisdiction under 28 U.S.C. § 1338(a) because the determination of fraud before the PTO necessarily involves a

II

This court reviews the district court's grant of summary judgment de novo, applying the same legal standards applied by the district court. Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1378 (Fed. Cir. 2008); U.S. Phillips Corp. v. Iwasaki Elec. Co., 505 F.3d 1371, 1374 (Fed. Cir. 2007). Summary judgment is appropriate where, after drawing all reasonable inferences in favor of the non-movant, there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986); Rubens v. Mason, 527 F.3d 252, 254 (2d Cir. 2008).

This court also reviews the district court's grant or denial of a motion to dismiss de novo. Adenta GmbH v. OrthoArm, Inc., 501 F.3d 1364, 1368 (Fed. Cir. 2007); Univ. of W. Va. Bd. of Trs. v. Vanvoorhies, 278 F.3d 1288, 1295 (Fed. Cir. 2002). Whether federal patent law preempts a state law claim is a question of law which we review de novo. Ultra-Precision Mfg., Ltd. v. Ford Motor Co., 411 F.3d 1369, 1376 (Fed. Cir. 2005).

III

The appellants allege that the district court erred in its determination that the Agreements did not constitute an unreasonable restraint of trade in violation of section 1 of the Sherman Act, and in its grant of Bayer's and the generic defendants' motions for summary judgment on Counts I-IV, as follows: (1) by not finding the Agreements to be per se unlawful, or at least applying a proper rule of reason analysis; (2) by finding the

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substantial question of patent law. See Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 808 (1988).

Agreements to be lawful because they fell within the "exclusionary zone" of the '444 patent; (3) by not considering the law of the regional circuits and government agencies in evaluating the Agreements; (4) by failing to appreciate the effects of the Agreements on other generic manufacturers; and (5) by not considering evidence showing that the Agreements preserved Barr's claim to the 180-day exclusivity period. We address each asserted error in turn.

A

According to the appellants, the Agreements allowed Bayer to exclude a horizontal competitor from the market not by enforcing its rights as a patentee, but instead by ceasing to enforce its rights and paying the competitor $398 million. The appellants contend that the district court should have concluded that the Agreements were per se unlawful or should have applied a proper rule of reason analysis. At a minimum, the appellants assert, the court should not have resolved the case on summary judgment, but instead should have presented it to a fact-finder to determine whether the Agreements constituted an unreasonable restraint on trade.[9]

The Sherman Act provides that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal." 15 U.S.C. § 1. Although by its terms, the Act prohibits any "restraint of trade," the Supreme Court "has long recognized that Congress intended to outlaw only unreasonable restraints." State Oil Co. v. Khan, 522

[9] Specifically, the appellants contend that there are genuine issues of material fact relating to whether the defendants received far more under the Agreements then they could have had Barr won the litigation against Bayer, invalidated the '444 patent, and entered the market. Further, the appellants aver that the court needs to assess the apparent strength of the patent at the time of the Agreements.

U.S. 3, 10 (1997). Courts will presumptively apply a "rule of reason" analysis to determine whether an agreement imposes an unreasonable restraint on competition. Texaco, Inc. v. Dagher, 547 U.S. 1, 5 (2006). Only agreements that have a "predictable and pernicious anticompetitive effect, and . . . limited potential for procompetitive benefit" are deemed to be per se unlawful under the Sherman Act. State Oil, 522 U.S. at 10. A finding of per se unlawfulness "is appropriate '[o]nce experience with a particular type of restraint enables the Court to predict with confidence that the rule of reason will condemn it.'" Id. (quoting Arizona v. Maricopa County Med. Soc'y, 457 U.S. 332, 344 (1982)). The Supreme Court has expressed reluctance to adopt per se rules where the economic impact is not immediately obvious. Id.

Since there was no basis for the district court to confidently predict that the Agreements at issue here would be found to be unlawful under a rule of reason analysis, we find no error by the court in declining to find them to be per se unlawful. Instead, the court properly went through a rule of reason analysis to determine whether the Agreements were in fact an unreasonable restraint of trade.

Under the law of the Second Circuit, the rule of reason analysis is a three-step process:

> First, the plaintiff bears the initial burden of showing that the challenged action has had an actual adverse effect on competition as a whole in the relevant market. Then, if the plaintiff succeeds, the burden shifts to the defendant to establish the pro-competitive redeeming virtues of the action. Should the defendant carry this burden, the plaintiff must then show that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition.

Clorox Co. v. Sterling Winthrop, Inc., 117 F.3d 50, 56 (2d Cir. 1997) (citations and internal quotations omitted). Typically, the starting point is to define the relevant market,

Geneva Pharms. Tech. Corp. v. Barr Labs., Inc., 386 F.3d 485, 495-96 (2d Cir. 2004), and to determine whether the defendants possess market power in the relevant market. United States v. Visa U.S.A., Inc., 344 F.3d 229, 238 (2d Cir. 2003). Although the precise role that market power plays in the rule of reason analysis is unclear, it may be a highly relevant factor. Id. at 238 n.4; Capitol Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., 996 F.2d 537, 546 (2d Cir. 1993).

Contrary to the contentions of the appellants, the court did undertake a full rule of reason analysis. It first determined that the relevant market is ciprofloxacin and that Bayer had market power within that market. Cipro II, 363 F. Supp. 2d at 523. It then determined that there was no evidence that the Agreements created a bottleneck on challenges to the '444 patent or otherwise restrained competition outside the "exclusionary zone" of the patent. Id. at 540. Thus, the court concluded that the plaintiffs had failed to demonstrate that the Agreements had an anti-competitive effect on the market for ciprofloxacin beyond that permitted by the patent. Id. Because the court concluded that the plaintiffs failed to meet their burden under the first step of the rule of reason analysis, it did not find it necessary to consider the second or third steps of the analysis. Id. at 541.

B

The appellants assert, however, that the district court erred in concluding that the Agreements were within the "exclusionary zone" of the '444 patent, in essence treating them as per se legal. According to the appellants, the patentee's right to exclude competition is not defined by the facial scope of the patent, but rather is limited to the right to exclude others from profiting from the patented invention. Under the

Agreements, the appellants argue, Bayer is seeking not simply to enforce its patent rights, but to insulate itself from competition and avoid the risk that the patent is held invalid.

The district court did not treat the Agreements as per se legal. Rather, the court simply recognized that any adverse anti-competitive effects within the scope of the '444 patent could not be redressed by antitrust law. United States v. Gen. Elec. Co., 272 U.S. 476, 485 (1926); E. Bement & Sons v. Nat'l Harrow Co., 186 U.S. 70, 91 (1902); see In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 201-02 (2d Cir. 2006); Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1312 (11th Cir. 2003); United States v. Studiengesellschaft Kohle, m.b.H., 670 F.2d 1122, 1127 (D.C. Cir. 1981). This is because a patent by its very nature is anticompetitive; it is a grant to the inventor of "the right to exclude others from making, using, offering for sale, or selling the invention . . . ." 35 U.S.C. § 154(a)(1); Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."). Thus, "a patent is an exception to the general rule against monopolies and to the right of access to a free and open market." Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945). The district court appreciated this underlying tension between the antitrust laws and the patent laws when it compared the anti-competitive effects of the Agreements with the "zone of exclusion" provided by the claims of the patent. See In re Tamoxifen, 466 F.3d at 201-02; Andrx Pharms., Inc. v. Elan Corp., 421 F.3d 1227, 1235 (11th Cir. 2005); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005); Valley Drug, 344 F.3d at 1312. Because the court found no anti-competitive effects outside the

exclusionary zone of the patent, it concluded that the Agreements were not violative of section 1 of the Sherman Act. Cipro II, 363 F. Supp. 2d at 540-41.

We find no error in the court's analysis. Pursuant to the Agreements, the generic defendants agreed not to market a generic version of Cipro until the '444 patent expired[10] and not to challenge the validity of the '444 patent, and Bayer agreed to make payments and optionally supply Cipro for resale. Thus, the essence of the Agreements was to exclude the defendants from profiting from the patented invention. This is well within Bayer's rights as the patentee. Furthermore, there is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation. Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1368 (Fed. Cir. 2001); Foster v. Hallco Mfg. Co., 947 F.2d 469, 477 (Fed. Cir. 1991). Settlement of patent claims by agreement between the parties—including exchange of consideration—rather than by litigation is not precluded by the Sherman Act even though it may have some adverse effects on competition.[11] Standard Oil Co. v. United States, 283 U.S. 163, 171 & n.5 (1931).

We disagree with the appellants that the fact that the generic defendants agreed not to challenge the validity of the '444 patent renders the Agreements violative of the antitrust laws. According to the appellants, there is a vital public interest in patent validity challenges to ensure that consumers are not burdened by unwarranted patent monopolies. Appellants assert that Congress underscored this public interest by providing in 35 U.S.C. § 282 that an issued patent carries only a rebuttable presumption

[10] Under the Cipro Supply Agreement, however, Barr was allowed to sell a competing ciprofloxacin product six months before the '444 patent expired.

of validity, which can be challenged in court. In fact, appellants argue, at the preliminary injunction stage, the patentee has the burden of establishing the likelihood of success on the merits of the patent's validity. Furthermore, the appellants contend, in the Hatch-Waxman Act, Congress provided the incentive of a 180-day exclusivity period to the first generic manufacturer to challenge a patent.

Settlements in patent cases, however, frequently provide that the alleged infringer will not challenge the validity of the patent. See, e.g., Flex-Foot, 238 F.3d at 1367, 1370; Diversey Lever, Inc. v. Ecolab, Inc., 191 F.3d 1350, 1351 (Fed. Cir. 1999); Interspiro USA, Inc. v. Figgie Int'l, Inc., 18 F.3d 927, 932 (Fed. Cir. 1994). Thus, the mere fact that the Agreements insulated Bayer from patent validity challenges by the generic defendants was not in itself an antitrust violation. Indeed, there is no evidence that the Agreements prevented challenges by other generic drug manufacturers to the validity of the '444 patent. In fact, four other generic manufacturers—Ranbaxy, Mylan, Schein, and Carlsbad—filed Paragraph IV ANDAs and initiated challenges of the validity of the patent.

C

The appellants urge this court to consider the legal standards applied by the regional circuits and government agencies in addressing Agreements involving exclusion payments in the context of the Hatch-Waxman Act, all of which, they assert, encompass greater antitrust scrutiny than the standard adopted by the district court. In particular, the appellants point to the Sixth Circuit's decision in In re Cardizem CD

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[11] Indeed, a sizable exclusion payment from the patent holder to the generic manufacturer is not unexpected under the Hatch-Waxman Act, where the relative risks of litigation are redistributed. Schering-Plough, 402 F.3d at 1074; see infra pp. 23-24.

Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003), upholding a summary judgment ruling by the district court that a reverse payment agreement is per se illegal. Further, the appellants assert that although the Eleventh Circuit in Valley Drug reversed the district court's ruling of per se illegality, it provided a more extensive analytical framework within which to review the settlement agreements on remand. And, in Schering-Plough, the appellants assert the Eleventh Circuit adhered to the standard in Valley Drug and recognized the need to evaluate the strength of the patent in determining whether reverse payments are unlawful. The appellants contend that the Federal Trade Commission ("FTC") advocates a rule of reason inquiry focusing on the amount of the payment and several other factors, although not requiring consideration of the validity of the patent. Finally, the appellants note that the Solicitor General has suggested that a reverse payment should be evaluated using a rule of reason approach and that "the strength of the patent as it appeared at the time at which the parties settled" should be considered in the analysis, citing Brief for the United States as Amicus Curiae at *12, Joblove v. Barr Labs., 127 S. Ct. 3001 (2007) (No. 06-830), 2007 WL 1511527. According to the appellants, only the Second Circuit in In re Tamoxifen, has concluded that a settlement between a patent holder and an alleged infringer in Hatch-Waxman litigation does not violate the antitrust laws provided the litigation is not baseless, although it recognized that such an approach shields settlement agreements involving "fatally weak" patents. Therefore, the appellants assert, the district court's treatment of the Agreements here was not in line with that of the other circuits, the FTC, and the Solicitor General, and we should reject the district court's approach in lieu of those other standards.

We find, however, the district court's analysis to be sound. As noted above, the district court applied a rule of reason analysis in assessing the lawfulness of the Agreements. In that analysis, it considered whether there was evidence of sham litigation or fraud before the PTO, and whether any anticompetitive effects of the Agreements were outside the exclusionary zone of the patent. The application of a rule of reason analysis to a settlement agreement involving an exclusion payment in the Hatch-Waxman context has been embraced by the Second Circuit, and advocated by the FTC and the Solicitor General. And, although the Sixth Circuit found a per se violation of the antitrust laws in In re Cardizem, the facts of that case are distinguishable from this case and from the other circuit court decisions. In particular, the settlement in that case included, in addition to a reverse payment, an agreement by the generic manufacturer to not relinquish its 180-day exclusivity period, thereby delaying the entry of other generic manufacturers. In re Cardizem, 332 F.3d at 907. Furthermore, the agreement provided that the generic manufacturer would not market non-infringing versions of the generic drug. Id. at 908 n.13. Thus, the agreement clearly had anti-competitive effects outside the exclusion zone of the patent. See Brief for the United States at *16 n.7, Joblove, 127 S. Ct. 3001 (No. 06-830); Brief for the United States as Amicus Curiae at *17, FTC v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05-273), 2006 WL 1358441. To the extent that the Sixth Circuit may have found a per se antitrust violation based solely on the reverse payments, we respectfully disagree.

The Eleventh Circuit in Valley Drug reversed a finding by the district court that settlement agreements constituted a per se violation of the antitrust laws because the court failed to consider the exclusionary power of the patent in its antitrust analysis. 344

F.3d at 1306, 1312. Although it rejected the court's condemnation of the agreements as a per se antitrust violation, it did not advocate application of a rule of reason analysis, finding such an analysis to be inappropriate given that the anticompetitive effects of the exclusionary zone of a patent are not subject to debate. Id. at 1312 n.27. In so holding, it emphasized that the subsequent declaration of invalidity did not render the patent's potential exclusionary effects irrelevant to the antitrust analysis. Id. at 1309. It did leave open the possibility, however, that an antitrust violation could be found in the extreme situation where there was evidence of fraud on the PTO or sham litigation. Id. at 1309 & n.21. On remand, it ordered the district court to consider the exclusionary potential of the patent, the extent to which provisions of the settlement agreement exceeded the scope of the patent, and the anticompetitive effects of those provisions. Id. at 1312.

This approach was followed by the Eleventh Circuit in Schering-Plough and Andrx Pharmaceuticals and by the Second Circuit in In re Tamoxifen. In re Tamoxifen, 466 F.3d at 212; Andrx Pharms., 421 F.3d at 1235; Schering-Plough, 402 F.3d at 1066. In Schering-Plough, the Eleventh Circuit set aside the decision by the FTC that the settlement agreements constituted an unreasonable restraint of trade. 402 F.3d at 1058. It noted that there was no evidence that the patent was invalid or that the litigation was a sham, and thus the proper analysis was whether the agreements restricted competition beyond the exclusionary effects of the patent. Id. at 1068. After reviewing the terms of the settlement agreements, it found that they were within the exclusionary zone of the patent and therefore protected by patent law. Id. at 1072. The Second Circuit, in In re Tamoxifen, similarly concluded that the validity of the patent need not be considered in the analysis of whether the settlement agreement violates the

antitrust laws unless the infringement suit was objectively baseless. 466 F.3d at 213. In that case, the patent holder settled with the generic manufacturer after losing on validity before the district court and while on appeal to this court. Id. at 193. In so holding, the Second Circuit recognized that alleged Sherman Act violations are generally evaluated under a rule of reason analysis. Id. at 201 n.13. It concluded that the presence of a reverse payment, or the size of a reverse payment, alone is not enough to render an agreement violative of the antitrust laws unless the anticompetitive effects of the agreement exceed the scope of the patent's protection. Id. at 212-13. Because the agreement did not extend to non-infringing products and did not create a bottleneck for other generic manufacturers, the court held that any anticompetitive effects were within the exclusionary power of the patent. Id. at 213-16.

We conclude that in cases such as this, wherein all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent. The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and the Eleventh Circuits and by the district court below and we find it to be completely consistent with Supreme Court precedent. See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 175-77 (1965) (holding that there may be a violation of the Sherman Act when a patent is procured by fraud, but recognizing that a patent is an exception to the general rule against monopolies).

In addition, we agree with the Second and Eleventh Circuits and with the district court that, in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment.[12] The FTC has also rejected the application of a post hoc analysis of the validity of the patent as part of the antitrust analysis. In its decision that led to the Eleventh Circuit appeal in Schering-Plough, the FTC concluded that "it would not be necessary, practical, or particularly useful for the Commission to embark on an inquiry into the merits of the underlying patent dispute when resolving antitrust issues in patent settlements." In re Schering-Plough Corp., No. 9297, 2003 WL 22989651, slip op. at 19 (F.T.C. Dec. 8, 2003). However, on petition for writ of certiorari, the FTC criticized the Eleventh Circuit's approach to evaluating the exclusionary potential of the patent because it "ignore[d] the most salient factor that gives rise to patent litigation and settlements, the existence of uncertainty regarding whether a patent is valid or . . . infringed by particular products." Petitioner's Opening Brief at *15, Schering-Plough, 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2105243. Similarly, here, the FTC argues that the district court erred by equating the exclusionary power of the patent with the scope of the patent claims without consideration of the uncertainty of patent validity. Corrected Br. of Amicus Curiae FTC in Supp. of Appellants 19. Apparently, the FTC, in recognizing the "probabilistic" nature of the

[12] Although certain statements by the Eleventh Circuit have been interpreted to mean that it advocated consideration of the validity of the patent, Brief for the United States at *16, Joblove, 127 S. Ct. 3001 (No. 06-830); Brief for the United States at *17-19, Schering-Plough 548 U.S. 919 (No. 05-273), the district court correctly noted that the Eleventh Circuit did not consider or rely on evidence of patent invalidity in either Valley Drug or Schering-Plough. Cipro II, 363 F. Supp. 2d at 525, 529.

patent interest, recommends that the "expected value" of the lawsuit at the time of the settlement be considered in the antitrust analysis. Petitioner's Opening Brief at *16, Schering-Plough, 548 U.S. 919 (No. 05-273); Reply Brief for the Petitioner at *6, Schering-Plough, 548 U.S. 919 (No. 05-273), 2005 WL 2652617.

The Solicitor General advocates that an appropriate antitrust analysis "should take into account the relative likelihood of success of the parties' claims, viewed ex ante." Brief for the United States at *12, Joblove, 127 S. Ct. 3001 (No. 06-830); Brief for the United States at *11, Schering-Plough, 548 U.S. 919 (No. 05-273). Practically, the Solicitor General proposes that, while the court need not conduct a full trial, it could conduct a limited evaluation of the merits of the patent claims. Brief for the United States at *13, Joblove, 127 S. Ct. 3001 (No. 06-830); Brief for the United States at *11 n.1, Schering-Plough, 548 U.S. 919 (No. 05-273). While the expected value of the lawsuit (considered in the approach advocated by the FTC) should relate directly to the relative strength of the claim (considered in the approach advocated by the Solicitor General), the distinction between the approaches advocated by the FTC and the Solicitor General may lie in the fact that the expected value of the lawsuit depends on the subjective views of the parties as opposed to objective evidence of validity. See Brief for the United States at *12, Schering-Plough, 548 U.S. 919 (No. 05-273).

We disagree that analysis of patent validity is appropriate in the absence of fraud or sham litigation. Pursuant to statute, a patent is presumed to be valid, 35 U.S.C. § 282, and patent law bestows the patent holder with "the right to exclude others from profiting by the patented invention." Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980). A settlement is not unlawful if it serves to protect that to which the

patent holder is legally entitled—a monopoly over the manufacture and distribution of the patented invention. In re Tamoxifen, 466 F.3d at 208-09. Thus, the district court correctly concluded that there is no legal basis for restricting the right of a patentee to choose its preferred means of enforcement and no support for the notion that the Hatch-Waxman Act was intended to thwart settlements. Cipro II, 363 F. Supp. 2d at 531-32. As Judge Posner remarked, if "there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation." Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 992 (N.D. Ill. 2003).

Accordingly, we find the analysis by the district court to be fully supported in law and to demonstrate that it was cognizant of the legal standards applied by the regional circuits and government agencies in addressing agreements involving exclusion payments in the context of the Hatch-Waxman Act.

D

The appellants next contend that the district court erred in reasoning that even though Bayer settled with Barr, other generic companies could still challenge the '444 patent and their incentive to challenge the patent would grow with the chance that the patent would be held invalid, rendering any anticompetitive effects of the Agreements short-lived. According to the appellants, while that reasoning may make sense outside the Hatch-Waxman context, it does not apply under Hatch-Waxman, where they allege generic manufacturers are less motivated to initiate and vigorously challenge a patent. The appellants contend that the incentives are significantly reduced in the Hatch-

Waxman context because any generic manufacturer that wishes to challenge the patent must first undertake the effort, time, and expense of filing a Paragraph IV ANDA. The appellants further assert that few generic manufacturers are capable of initiating such a challenge and any challenge would be significantly delayed. Thus, the appellants argue that the brand name manufacturer, by paying off the first Paragraph IV ANDA filer, can protect its monopoly from competition for years—particularly near the end of the patent term—even if its patent is "fatally weak." It is that delay in challenge by generic manufacturers that is emphasized by the appellants here, since there is no dispute that four other generic manufacturers ultimately challenged the validity of the '444 patent.

While we recognize that the Hatch-Waxman Act creates certain burdens for generic manufacturers, it also provides significant benefits. First, it streamlines the process of obtaining FDA approval to market a generic version of a drug without having to go through the rigorous new drug application ("NDA") process that the patent holder is required to do. Compare 21 U.S.C. § 355(j)(2)(A) with 355(b)(1). See Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990). Thus, the generic drug manufacturers can piggyback on the safety and efficacy studies conducted by the patent holder. Second, it allows the generic manufacturers to challenge the validity of a patent simply by filing a Paragraph IV ANDA. 21 U.S.C. § 355(j)(2)(A)(vii), (5)(C)(i); see Eli Lilly, 496 U.S. at 677. Thus, as explained by the Eleventh Circuit, the Hatch-Waxman Act redistributes the relative risks between the patent holder and generic manufacturers, allowing generic manufacturers to challenge the validity of the patent without incurring the costs of market entry or the risks of damages from infringement. Schering-Plough, 402 F.3d at 1074. Thus, the district court reasonably concluded that the incentive to mount a

challenge would increase with the chance that the patent would be held invalid. Cipro II, 363 F. Supp. 2d at 534. Further, the district court noted that there was no evidence that the Agreements created a bottleneck preventing generic challenges to the '444 patent. Id. at 540. Indeed, the patent was subsequently challenged by four other generic manufacturers and was upheld as valid.

E

Finally, the appellants contend that the district court erred in not considering evidence showing that the Agreements preserved Barr's claim to the 180-day exclusivity period, which served the defendants' joint interest in protecting the Cipro monopoly from generic competition. According to the appellants, the district court refused to consider the evidence in Cipro II because it had earlier denied the plaintiffs' motions for partial summary judgment in Cipro I. But, the appellants assert, the district court should have considered the evidence anew in Cipro II, because: (1) the plaintiffs were now the non-moving parties and thus the evidence should have been considered in the light most favorable to the plaintiffs; and (2) at issue was whether the Agreements had an actual adverse effect on competition in the relevant market, whereas in Cipro I the issue was the per se illegality of the Agreements. The appellants aver that the evidence raised genuine issues of material fact regarding whether the Agreements preserved Barr's claim to the 180-day exclusivity period, delayed and deterred other generic manufacturers from entering the ciprofloxacin market, and thus had an actual adverse effect on competition.

Again, we find no error in the district court's analysis. In addressing whether the Agreements restrained competition outside the scope of the '444 patent, the court

observed that the only legitimate allegation by the plaintiffs was that the 180-day exclusivity period had been manipulated by Barr. Cipro II, 363 F. Supp. 2d at 540. However, the court noted that that theory had already been addressed in Cipro I. Specifically, in Cipro I, the court determined that the Agreements did not create a "bottleneck" for future Paragraph IV ANDA filers because Barr had no right to the 180-day exclusivity period. 261 F. Supp. 2d at 243. That was because at the time of the Agreements, the FDA regulation in effect conditioned the first Paragraph IV ANDA filer's right to the 180-day exclusivity period on a "successful defense" of its Paragraph IV ANDA against the patent holder. Id.; see 21 C.F.R. § 314.107(c)(1) (1998), revoked 63 Fed. Reg. 59710, 59711 (Nov. 5, 1998). However, Barr acknowledged in the consent judgment both its infringement and the validity of the '444 patent, thereby ending the underlying litigation. Cipro I, 261 F. Supp. 2d at 243. More importantly, as part of the Agreements, Barr converted its Paragraph IV ANDA to a Paragraph III ANDA. Id. Thus, the court concluded that Barr had failed to satisfy the successful defense requirement necessary to be eligible for the 180-day exclusivity period. Id.

We do not know what evidence the plaintiffs believe would have created a genuine issue of material fact had it been considered by the district court in Cipro II. There appears to be no dispute about the contents of the consent judgment and the Agreements, and there does not appear to be a dispute about what was contained in the FDA regulation that was in effect at the time. Although the appellants make much of the uncertainty in the law regarding the validity of the "successful defense"

requirement,[13] we find no merit to that argument. The district court acknowledged that two circuit courts issued opinions in April 1998, more than a year after the Agreements were executed, striking down the FDA regulation. Cipro I, F. Supp. 2d at 243-44 (citing Mova Pharm. Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998); Granutec, Inc. v. Shalala, 139 F.3d 889 (4th Cir. 1998)). The court further noted that the FDA ultimately removed the successful defense requirement from the regulation in November 1998. Cipro I, F. Supp. 2d at 244 (citing 63 Fed. Reg. 59710, 59711 (Nov. 5, 1998)). Nevertheless, the court correctly concluded that "the fact still remains that the requirement was in effect at the time of the [Agreements]." Cipro I, F. Supp. 2d at 244; see Tamoxifen, 466 F.3d at 218 (concluding that because the established law at the time of the settlement agreement required that a generic manufacturer must successfully defend an infringement lawsuit in order to obtain exclusivity, the generic manufacturer had no claim to the exclusivity period despite the terms of the agreement). Furthermore, the court appreciated that even without the successful defense requirement, there was still no support for the claim that Barr retained the 180-day exclusivity period after amending from a Paragraph IV ANDA to a Paragraph III ANDA.[14] Cipro I, F. Supp. 2d at 247. Finally, the court recognized that since the

[13] At oral argument, the appellants emphasized that Mylan was delayed for two-and-a-half years in filing its ANDA and challenging the patents because it believed that Barr was entitled to the 180-day exclusivity period. Oral Arg. at 5:56-6:29, 6:49-7:02, available at http://www.cafc.uscourts.gov/oralarguments/mp3/2008-1097.mp3. They further asserted that because of the delay, none of the generic challengers raised the issue of inequitable conduct. Id. at 7:05-7:57.

[14] Although the Agreements apparently did contain a provision preserving the option for Barr to reamend to a Paragraph IV ANDA (presumptively for the purpose of reclaiming the 180-day exclusivity period) if the '444 patent was subsequently declared by a court to be invalid or unenforceable, that provision does not change the

Agreements were executed, Bayer has sued four other generic manufacturers that filed ANDAs and defended against invalidity counterclaims; thus, the Agreements did not prevent other generic manufacturers from challenging the '444 patent. Id. We find no error by the district court in declining to consider anew the evidence allegedly showing that the Agreements preserved Barr's claim to the 180-day exclusivity period, and in concluding that the Agreements did not create a "bottleneck" for other generic manufacturers.

Accordingly, we affirm the district court's grant of summary judgment on Counts I-IV, holding that the Agreements were not violative of section 1 of the Sherman Act since all anticompetitive effects were within the exclusionary power of the '444 patent.

IV

Count V alleges that Bayer violated state antitrust and consumer protection laws by fraudulently obtaining the '444 patent and enforcing it through sham litigation. The district court dismissed Count V as preempted by federal patent law. Cipro II, 363 F. Supp. 2d at 547.

The appellants challenge the district court's dismissal of Count V, arguing under Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318 (Fed. Cir. 1998), and Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059 (Fed. Cir. 1998), that the court erred in concluding that their state law monopolization claims are preempted by federal patent law because preemption does not apply when the patent was procured

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analysis. Under the FDA regulations in effect at the time of the Agreements, the first generic manufacturer was not entitled to the 180-day exclusivity period unless it had satisfied the successful defense requirement. Furthermore, since the option was never exercised, there was no evidence of an actual adverse effect on competition due to that provision. See Clorox, 117 F.3d at 56.

by fraud. Further, the appellants contend that the district court erroneously concluded that no tortious conduct in the marketplace had been alleged, ignoring Bayer's lawsuit against Barr seeking to enforce a fraudulently procured patent. According to the appellants, the district court's reliance on Semiconductor Energy Laboratory Co. v. Samsung Electronics Co., 204 F.3d 1368 (Fed. Cir. 2000), and Abbott Laboratories v. Brennan, 952 F.2d 1346 (Fed. Cir. 1991), is misplaced because neither case involves a state law antitrust claim based on wrongful enforcement of a patent procured by fraud. The appellants assert that an antitrust claim under Walker Process is distinguishable from an inequitable conduct claim because it contains the additional elements of an antitrust claim, namely, market power and antitrust injury. The monopolization claims here, the appellants contend, like those in Dow Chemical Co. v. Exxon Corp., 139 F.3d 1470 (Fed. Cir. 1998), have elements other than inequitable conduct before the PTO—and therefore are not preempted by federal patent law. Finally, the appellants argue that because antitrust is a field traditionally regulated by the states, there is a presumption against preemption of state law, and Congress has made no express legislative statement to overcome that presumption.

It is not clear that the district court considered the portions of Hunter Douglas and Nobelpharma that the appellants rely on in their brief. However, the result in this case would not change even if we were to adopt the appellants' interpretation of these cases because the district court determined, and we agree, that no fraud occurred. In light of this, the district court's disposition of Count V was not erroneous.

V

For the foregoing reasons, we affirm the grant of summary judgment by the

District Court for the Eastern District of New York that the Agreements were not in violation of section 1 of the Sherman Act because any anti-competitive effects caused by the Agreements were within the exclusionary zone of the patent. We further affirm the court's dismissal of the state antitrust claims.

AFFIRMED