Supreme Court Lets So-Called "Reverse Payment" Stand

On March 7, 2011, the U.S. Supreme Court denied a petition for a writ of certiorari filed by various drug purchasers in which they asked the Court to review so-called reverse payments, arrangements in which patent litigation brought by brand-name drug manufacturers against generic manufacturers is settled by a payment by the brand-name manufacturer and an agreement by the generic manufacturer not to produce the challenged product. The Court's denial let stand a Second Circuit decision that rejected antitrust claims based on a settlement between Bayer AG, the owner of a patent for ciprofloxacin ("Cipro"), and Barr Laboratories, Inc., a generic manufacturer that had challenged the patent, in which Bayer paid Barr $398 million and Barr agreed to defer sale of its product as part of the settlement (the "Cipro case"). The Supreme Court's decision not to review the Cipro case leaves standing the petitioner's alleged three-way split in the federal courts of appeals regarding the role of antitrust law when brand-name pharmaceutical and generic drug manufacturers settle patent infringement litigation.

Background

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, provides generic manufacturers with a streamlined process to obtain Food and Drug Administration approval for marketing a generic version of a brand-name drug. It also allows generic manufacturers to attempt to avoid the blocking effect of the branded manufacturer's patent by simply filing a Paragraph IV certification in its abbreviated new drug application alleging that the relevant patent is invalid or will not be infringed by the manufacture and sale of the generic drug. The patent holder can then file suit against the generic manufacturer for infringement.

Patent holders and generic manufacturers frequently enter into patent settlement agreements rather than risk the uncertainty and expense of litigation. Sometimes these arrangements provide that the branded company make payments to the alleged infringers in exchange for their promise to delay the marketing of the generic products. Such settlement agreements have been challenged by the Federal Trade Commission and by purchasers of the patented products, and have been criticized by consumer groups.

In *Arkansas Carpenters Health and Welfare Fund v. Bayer*, 604 F.3d 98 (2d Cir. 2010), the case on appeal to the Supreme Court, Bayer, the brand-name manufacturer, made a payment totaling $398.1 million to Barr, the generic manufacturer, as part of a settlement in which Barr agreed not to (1) challenge the validity or enforceability of Bayer's patent for Cipro or (2) market its generic version of the patent until after it expired.

Various purchasers of Cipro filed antitrust actions in state and federal courts against Bayer and Barr, alleging that the settlement agreement restrained trade in violation of federal antitrust law because Bayer, in plaintiffs' terms, paid Barr not to compete, an action that, in most other contexts, would likely constitute a *per se* violation of Section 1 of the Sherman Act. The cases were ultimately consolidated in the Eastern District Court of New York. Both the plaintiffs and defendants filed cross-motions for summary judgment in the consolidated action regarding whether the agreement had anticompetitive effects prohibited under Section 1 of the Sherman Act.

Second Circuit Decision

The Eastern District Court of New York granted summary judgment to the defendants, concluding that, under a rule of reason analysis, any adverse effects on competition stemming from the agreement were within the "exclusionary zone" of the patent (*i.e.*, the restricted activities were limited to those that would infringe the patent) and therefore could not be redressed by antitrust law. Finding no evidence indicating that the agreement restrained competition beyond the scope of the patent, the court held that the plaintiffs failed to show that the agreement had any anticompetitive effects on the market for Cipro beyond that permitted under the patent.

The Second Circuit affirmed, stating that the district court properly employed the standard of analysis required by the Second Circuit's prior holding in *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006). Specifically, the *In re Tamoxifen* court held that so-called reverse payments alone do not render an agreement violative of antitrust laws unless the anticompetitive effects of the agreement exceed the scope of the patent's protection. Because "Barr's agreement to refrain from manufacturing generic Cipro only encompasses conduct that would infringe Bayer's patent rights," the Second Circuit allowed the district court's ruling to stand. *See Arkansas Carpenters supra*. The Second Circuit denied a Petition for Rehearing and Rehearing En Banc in September 2010.

Plaintiffs also appealed the district court decision to the Federal Circuit. The Federal Circuit held that it was required to decide the case "[u]nder the law of the Second Circuit" and relied on *In re Tamoxifen Citrate Antitrust Litig*. as binding precedent. It ruled in favor of the defendants. See *In re Ciprofloxacin Hydrochloride Antitrust Litig*., 544 F.3d 1323 (Fed. Cir. 2008).

Circuit Split

In the petition for certiorari, the plaintiffs argued that the Supreme Court should review this case because of the inconsistent approaches taken by several circuit courts as to the proper standard for determining whether a settlement that includes payment from the patent-owner to the challenger is anticompetitive, and, thus, illegal. The plaintiffs alleged that the Sixth and D.C. Circuits focus on the strength of the patent, taking the position that such payment constitutes substantial economic evidence that, in the litigants' view, the patent was not strong enough on its own to prevent competition. See *In re Cardizem CD 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); see also *Andrx Pharm. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001) (reversing the dismissal of the antitrust claims of another generic competitor whose market entry was blocked by the settlement agreement).

The plaintiffs argued that the Eleventh Circuit rejects this "patent strength" standard and instead, in *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003) and *Schering-Plough v. FTC*, 402 F.3d 1056 (11th Cir. 2005), endorses an "ex post judicial determination" of the merits of the underlying patent case in determining whether exclusive payments are unlawful.

The plaintiffs further alleged that both the Second Circuit and Federal Circuit, on the other hand, eschew each of these standards and rely on the rebuttable presumption of patent validity. Under this approach, because patents should be presumed valid absent fraud on the Patent & Trademark Office or sham litigation, a court should conclude that a patent holder would have won the patent case and, therefore, that a reverse payment is not anticompetitive.

Finally, the plaintiffs also argued that review of the Second Circuit's case is necessary because the Second Circuit's standard conflicts not only with Supreme Court precedent, but also with the spirit of the

Hatch-Waxman Act in which Congress sought to speed the process of getting generic drugs into the hands of patients at reasonable prices.

Federal Trade Commission, Department of Justice, and Legislative Positions

The Federal Trade Commission ("FTC") has consistently taken the position that patent settlements between brand-name and generic drug manufacturers should be subject to careful antitrust scrutiny. The Antitrust Division of the Department of Justice, which previously adhered to a contrary position, recently shifted to a position more consistent with that of the FTC. Both agencies filed amicus briefs in support of the Supreme Court's review of the Cipro case. The government's primary argument is that payments by patent-owners to patent-challengers in such settlements are essentially payments to potential competitors not to compete and that the Second Circuit's decision misconstrued the policies and incentives established in the Hatch-Waxman Act. The FTC's position in this case follows, and is consistent with, its previously unsuccessful attempt to obtain Supreme Court review of both the *Tamoxifen* and *FTC v. Schering-Plough* cases.

The FTC has also supported legislative changes to ban some types of payments between brand-name and generic manufacturers. Senator Herb Kohl (D-WI) has again introduced legislation to provide the FTC greater enforcement authority over drug patent settlements. His most recent bill, the Preserve Access to Affordable Generics Act (S. 27), would empower the FTC to bring enforcement actions against so-called reverse payment settlements, which would be declared unlawful unless the parties can demonstrate that "the pro-competitive benefits of the agreement outweigh the anti-competitive effects of the agreement." While the FTC has not yet taken a public position on Senator Kohl's bill, its prior support of legislation in this arena suggests that it is likely to support similar efforts in this session of Congress.

Significance of the Supreme Court's Denial

In theory, there is no precedential effect of a denial of certiorari, and in the instant case only seven justices were available to determine whether to grant certiorari (Justices Sotomayor and Kagan recused themselves). However, the Court's determination not to grant the petition, together with the Court's refusal to take on the issue in the past, may give comfort to parties seeking to settle cases like the Cipro case and wishing to rely on the approaches taken by the Second and Eleventh Circuits in analyzing such settlements.

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