

# Pay-for-Delay May Require a New Prescription

*Part Two of a Two-Part Series*

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*Part One of this series discussed common IP settlement terms that may give rise to antitrust liability and how the analysis of whether a settlement agreement violates the antitrust laws depends upon many factors that are specific to the underlying facts. This second installment addresses recent challenges by the government and private plaintiffs to settlements between brand name and generic drug manufacturers, and how these challenges have further refined the antitrust framework for analyzing patent litigation settlement agreements in the pharmaceutical industry.*

## **INTRODUCTION**

Reverse payment, or “pay-for-delay,” patent settlements involve payments by pharmaceutical patent owners to potential manufacturers of generic versions of patented drugs in exchange for their agreement to refrain from entering the market. Patent owners are willing to pay a premium to delay a generic drug’s market entry because of the impact that a lower-priced generic would have on their sales. Antitrust concerns may arise when the decreased competition harms consumers; however, whether these settlements unreasonably restrain competition is widely debated. Courts routinely uphold such agreements where they do not exceed the scope of the patent’s protections, while government agencies have sought more stringent treatment under the antitrust laws. The Second Circuit’s recent decision in an appeal from the Ciprofloxacin MDL, *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, Nos. 05-2851-cv(L), 05-2852-cv(CON), 2010 U.S. App. LEXIS 8865 (2d Cir. Apr. 29, 2010) (“*Cipro*”), however, shows that courts may be rethinking their approach. Although the court upheld a reverse payment settlement, it simultaneously invited a petition for rehearing “in banc” based on concerns with its own precedent.

## **REGULATORY BACKGROUND**

Reverse payment settlements arise out of the Hatch-Waxman Act, which streamlined the application process for generic versions of FDA-approved branded drugs. Generic drug manufacturers can seek FDA approval without having to re-establish the drug’s safety and effectiveness by filing an Abbreviated New Drug Application (“ANDA”). An ANDA filer must certify that its generic drug is the bioequivalent of the branded drug and that the branded firm’s patent is “invalid or will not be infringed” by the generic drug (“Paragraph IV Certification”). See 21 U.S.C. § 355(j)(2)(A).

Filing a Paragraph IV certification is considered an act of infringement under the Hatch-Waxman Act and requires the branded manufacturer to sue within 45 days of receiving notice of the filing. Filing suit also triggers a stay of final FDA approval of the generic for 30 months following notice or until the court decides upon the alleged invalidity/infringement. Where the court finds no infringement or an invalid patent, the first Paragraph IV filer has the exclusive right to market its generic version for 180 days. Patent holders pay substantial sums to Paragraph IV filers to limit generics competition, and in exchange, Paragraph IV filers — who have yet to incur the costs of entering the market — agree to delay that entry and drop their invalidity challenge.

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## COURTS AND AGENCIES DIVIDED

There is a sharp divide among the courts and government agencies as to whether reverse payment settlements violate the Sherman Act. Several courts have upheld reverse payment settlements where the agreement's exclusionary effects do not exceed the scope of the patent's protections, thus giving no more exclusionary power than the patent holder is otherwise entitled to. *See, e.g., In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006) ("*Tamoxifen*"); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) ("*Schering*"); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) ("*Cipro* (Fed. Cir.)"). A patent's protections are limited by the express terms of the patent's numbered claims, its temporal breadth, and the litigation risk of invalidation. *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1296-97 (S.D. Fla. 2005) ("*Terazosin*").

The Second Circuit's *Tamoxifen* decision best illustrates the scope-of-the-patent standard in reverse payment cases: Unless the patent is fraudulently procured or a suit for its enforcement is objectively baseless, no cognizable market injury exists "as long as competition is restrained only within the scope of the patent." 466 F.3d at 213 (citation omitted); *see also Schering*, 402 F.3d at 1068 (same); *Cipro* (Fed. Cir.), 544 F.3d at 1336 (same). Neither the fact of a reverse payment nor its size alone is enough to render an agreement anticompetitive. *Tamoxifen*, 466 F.3d at 212-13. The agreement in *Tamoxifen* fell within the patent's scope because, as a "compound" patent that necessarily excludes all generic versions, the *Tamoxifen* patent would be infringed upon by any generic alternative. *Id.* at 214.

Two other courts struck down reverse payment settlements as *per se* illegal after considering whether the settlement exceeded the scope of the patent's protections. *See, e.g., In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) ("*Cardizem*"); *Terazosin*, 352 F. Supp. 2d at 1319. In *Cardizem*, the Sixth Circuit found a reverse payment settlement to be a classic restraint of trade between competitors "presumed to have the effect of reducing competition in the market." 332 F.3d at 911. The court also implicitly recognized in dicta that the agreement exceeded the patent's scope, noting that the parties' settlement bolstered the patent's effectiveness. *See Id.* at 908. Correspondingly, courts have distinguished *Cardizem* by finding that its settlement effectively exceeded the patent's scope by requiring the generic manufacturer to refrain from marketing non-infringing drugs and to agree not to relinquish its 180-day exclusivity period, thereby blocking other generic market entrants. *See, e.g., Tamoxifen*, 466 F.3d at 213-15. In *Terazosin*, the Southern District of Florida explicitly found the agreement before it *per se* illegal because it exceeded the patent's scope. 352 F. Supp. 2d at 1314-15. The court focused on the patent's temporal breadth, which included its termination date and an assessment of the underlying infringement/invalidity suit. Moreover, the court was not impelled to uphold the interim agreement because it failed to "resolve or even simplify" the parties' dispute. *Id.* at 1309.

Government agencies have condemned reverse payment settlements regardless of the patent's scope. For example, a recent FTC report states that courts upholding such settlements have "misapplied" the law. *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, at 1 (Jan. 2010), available at [www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf](http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf). Similarly, as discussed below, the

DOJ's brief in *Cipro* argued in part that such settlements presumptively violate the Sherman Act. Brief for the United States, *Cipro*, at 10 (2d Cir. July 6, 2009) ("*Cipro* Brief").

### **THE CIPRO DECISION**

In *Cipro*, the Second Circuit upheld another reverse payment settlement. There, direct and indirect purchasers challenged a settlement where Bayer paid Barr, the first Paragraph IV filer, \$398.1 million in exchange for Barr's promise not to sell its generic product until Bayer's patent expired. The trial court granted summary judgment for the defendants, finding that any adverse effects on competition under the settlement terms were within the patent's scope. 2010 U.S. App. LEXIS 8865, at \*1, \*8-\*11 & n.8.

Prior to rendering its decision, the Second Circuit invited the DOJ to brief the reverse payment settlement issue. The DOJ reiterated its view that the *Tamoxifen* standard is "incorrect" because it allows patent holders to contract out of the "significant risk of invalidation through litigation" and effectively bars the courts' review of the agreement. *Cipro* Brief at 6, 14-15; *see also* Brief for the United States as Amicus Curiae, *Jobless v. Barr Labs., Inc.*, No. 06-830, at 1 (S. Ct. May 2007). The DOJ also argued that reverse payment settlements are presumptively illegal and rebutted only by showing that the settlement did not unreasonably restrain competition. *Cipro* Brief at 21-29.

In its opinion, the Second Circuit noted the DOJ's contrary view, but stated it was "bound" to follow *Tamoxifen*. The court found the settlement was within the patent's scope because: 1) there was no restriction on marketing non-infringing products; 2) a generic version would necessarily infringe the branded firm's compound patent; and 3) other generic manufacturers were not barred from challenging the patent. *Cipro*, 2010 U.S. App. LEXIS 8865, at \*17, \*20-\*23 (citing *Tamoxifen*, 466 F.3d at 213-15).

Because of the "exceptional importance" of the antitrust implications of reverse exclusionary payment settlements," however, the court invited the plaintiffs to petition for a rehearing before the full Court of Appeals to allow it "an opportunity to revisit the issues in play in *Tamoxifen* and to analyze the competing interests that underlie antitrust challenges" to these settlements, recognizing:

- (1) the DOJ's "urg[ing]" of the court to repudiate *Tamoxifen*;
- (2) the evidence that the practice of entering into reverse payment settlements has increased since *Tamoxifen*;
- (3) the criticism of such settlements from the principal drafters of the Hatch-Waxman Act; and
- (4) the view that *Tamoxifen* was based "in no small part" on the erroneous belief that the 180-day exclusivity period was available to others beyond the first ANDA filer.

*Id.* at \*1, \*28-\*33 (citation omitted). In light of the court's invitation, which "further evidence[s] that courts are rethinking their approach to pay-for-delay settlements" (FTC Press Release, *available at* [www.ftc.gov/opa/2010/04/cipro.shtm](http://www.ftc.gov/opa/2010/04/cipro.shtm)), and the heightened scrutiny of these settlements by the legislative and executive branches (*see, e.g.*, Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009); Concurring Statement of Commissioner Jon

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Leibowitz, *FTC v. Watson Pharms.* (Feb. 2, 2009), available at [www.ftc.gov/speeches/leibowitz/090202watsonpharm.pdf](http://www.ftc.gov/speeches/leibowitz/090202watsonpharm.pdf), it comes as no surprise that plaintiffs continue to challenge these settlements. *See, e.g.*, Brief of Appellants (Redacted), *In re Cipro Cases I & II*, No. D056361 (Cal. Ct. App. May 14, 2010).

## **CONCLUSION**

As we have shown in our two-part series, whether an IP settlement violates the antitrust laws depends on the underlying facts. Understanding the existing — and potentially changing — antitrust framework for analyzing IP settlements, particularly reverse payment settlements, is a critical step in assessing potential antitrust liability.

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