Second Circuit Panel Invites Reconsideration of *Tamoxifen* Rule Upholding Reverse Payment Settlements

On April 29, 2010, the Second Circuit Court of Appeals upheld a "reverse payment" settlement of Hatch-Waxman patent litigation in *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, No. 05-2851 (2d Cir. April 29, 2010), widely known as the "Cipro®" antitrust litigation. In doing so, the court relied on the prior panel decision in *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d. Cir. 2005), which held that such a settlement does not violate the antitrust laws as a matter of law "as long as competition is restrained only within the scope of the patent." At the same time, however, the *Arkansas Carpenters* panel took the unusual step of inviting the plaintiffs to seek *en banc* reconsideration, so that the full Second Circuit could revisit the rule set forth by *Tamoxifen*, and explained why it believes such reconsideration is necessary.

Under the Hatch-Waxman Act, a company seeking to market a generic version of an FDA-approved brand-name drug must file an Abbreviated New Drug Application ("ANDA") with the FDA, demonstrating that its generic version is "bioequivalent" to the branded product. In addition, if the generic manufacturer wants to enter the market *before* any patents covering the product expire, it must give notice to the brand-name manufacturer regarding why those patents are invalid or would not be infringed by the proposed generic product. If the brand-name manufacturer sues for patent infringement within 45 days of receiving such notice, FDA approval of the generic version is automatically stayed for 30 months. The first ANDA filer to challenge the patents receives a 180-day period after FDA approval is granted to market its product without competition from other generics (the "180-day exclusivity period").

At issue in *Arkansas Carpenters* was a Hatch-Waxman patent litigation settlement relating to the antibiotic ciprofloxacin hydrochloride, marketed by Bayer under the brand name Cipro®. Bayer owned a patent on the ciprofloxacin hydrochloride compound, which expired in 2003. In 1991, Barr Laboratories filed an ANDA seeking FDA approval to market a generic version of Cipro®, and Bayer sued Barr for patent infringement. Shortly before trial, the parties entered into a settlement agreement in which Bayer agreed to make an immediate payment to Barr of $49 million, as well as quarterly payments of $12 to $17 million until six months before the patent expired; the payments ultimately totaled $398 million. Bayer also agreed to allow Barr to sell branded Cipro® during the six-month period just prior to the expiration of the patent. Barr conceded the patent's validity and agreed not to enter the market with a generic version or file further challenges to the patent prior to its expiration, and relinquished its right to the 180-day exclusivity period, but Barr retained the right to attempt to re-obtain the exclusivity period if another generic manufacturer succeeded in invalidating the patent. This kind of settlement is known as a "reverse payment" settlement because, instead of a payment by the defendant to the plaintiff to settle the action, the plaintiff pays the defendant.

In 2000, direct and indirect purchasers of Cipro® filed antitrust lawsuits in federal court against Bayer and Barr in the Eastern District of New York. They alleged that the settlement agreement violated Section 1 of the Sherman Act, which prohibits contracts or conspiracies in restraint of trade, because Bayer "paid its potential competitors hundreds of millions of dollars not to challenge its patent." The plaintiffs claimed that, absent the "reverse payment" settlement, a generic version of Cipro® would have entered the market sooner, and consumers would have paid less for the drug. The district court granted summary judgment

for the defendants, holding that any adverse effects on competition from the settlement agreements were not outside the "exclusionary zone" of the patent, and that the agreements did not allow Barr to "manipulate the exclusivity period to obstruct subsequent challengers of the patent."

The Second Circuit affirmed summary judgment against the direct purchasers, after finding that it was "bound to review [the settlement] under the standard adopted in *Tamoxifen*."[1] That decision held that a "reverse payment" settlement is not necessarily barred by the antitrust laws because a patent holder is entitled to protect its "lawful monopoly over the manufacture and distribution of the patented product." Under *Tamoxifen*, a settlement agreement will not exceed the scope of the patent, and is therefore lawful, where "(1) there was no restriction on marketing non-infringing products; (2) a generic version of the branded drug would necessarily infringe the branded firm's patent; and (3) the agreement did not bar other generic manufacturers from challenging the patent."

It is apparent that the *Arkansas Carpenters* panel only grudgingly upheld the Cipro® settlement agreement, which it characterized as a "pay-for-delay" settlement, because it was "bound" to follow *Tamoxifen* by the precedent rules of the Second Circuit. In fact, citing the "'exceptional importance' of the antitrust implications of reverse exclusionary payment settlements of patent infringement suits," the panel took the unusual step of expressly inviting the plaintiffs to seek *en banc* reconsideration of their decision in order to give the Second Circuit an opportunity to overrule *Tamoxifen*. The court also set out the reasons why it believed "there are compelling reasons to revisit *Tamoxifen*." First, "reverse payment" settlements have both increased and been widely criticized since *Tamoxifen* (including by the Federal Trade Commission and United States in *amicus* briefs, and by a principal drafter of the Hatch-Waxman Act). Second, according to the *Arkansas Carpenters* panel, *Tamoxifen* was based on an erroneous understanding of the Hatch-Waxman Act's provisions regarding the 180-day exclusivity period.

"Reverse payment" settlements have now been upheld by appellate courts in the Second, Eleventh and Federal Circuits, and all of their decisions rely on a test similar to that set out in *Tamoxifen*. Only a single decision in the Sixth Circuit has found a "reverse payment" settlement to be *per se* illegal. However, there have been numerous legislative proposals to prohibit such settlements, and the FTC continues to challenge them under the Sherman and FTC Acts. In fact, shortly after the *Arkansas Carpenters* decision was issued, FTC Chairman Jon Leibowitz stated that it is "further evidence that courts are rethinking their approach to pay-for-delay settlements," and vowed that "the FTC will continue to explain, in court and in the halls of Congress, why these sweetheart deals for drug companies are such a bad deal for American consumers and taxpayers."

In short, while, even after *Arkansas Carpenters*, the balance of authority continues to support the legality of "reverse payment" settlements, it appears that the last word on this issue has not yet been spoken. Companies considering settling Hatch-Waxman patent infringement litigation need to be mindful of what may be a changing landscape.

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[1] Because they included allegations of *Walker-Process* fraud, the claims of the indirect purchasers were appealed to the Federal Circuit Court of Appeals, rather than the Second Circuit. The Federal Circuit ultimately affirmed the district court on the indirect purchaser claims, agreeing with the district court's conclusion that the settlement did not restrain competition beyond the exclusionary scope of the patent. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1320 (Fed. Cir. 2008).

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