CLIENT ALERT

Second Circuit Wants Full Court Review of Reverse Exclusionary Settlement Payments

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A Second Circuit panel has invited an *en banc* or full court review of a "reverse exclusionary settlement payments" case that may ultimately reach the Supreme Court. The case is *Arkansas Carpenters Health and Welfare Fund v. Bayer A.G.*, Nos. 05-2851-cv(L) and 05-2852-cv(CON) (2d. Cir. Apr. 29, 2010). The opinion is attached.

1. Reverse Exclusionary Settlement Payments

The Drug Price Competition and Patent Term Restoration Act of 1984 - commonly known as the "Hatch-Waxman Act" - enables generic manufacturers to enter the market for a particular drug before the branded manufacturer's patent has expired through the filing of a pre-expiration challenge. At the same time, the Hatch-Waxman Act considers the pre-expiration challenge as infringing activity that could be the basis for the branded manufacturer suing the generic competitors.

Hatch-Waxman litigation frequently settles with the branded manufacturer (the patent holder) paying the generic competitor (the alleged infringer) in exchange for an agreement by the generic company not to enter the market, usually for a fixed period of time. Because the owner of the patent pays the alleged infringer, these settlements are colloquially known as "pay-for-delay" settlements and are more formally described as reverse exclusionary settlement payments.

These reverse settlement agreements potentially raise an antitrust issue: whether the branded manufacturer's payment for delayed entry by the generic competitor into the market is part of the patent holder's patent rights or whether it is an illegal market-sharing agreement between the patent holder and the generic manufacturer that may violate Section One of the Sherman Act.

There is a sharp divide on this question.

On the one hand, both the Federal Trade Commission and the United States Department of Justice question the validity of reverse exclusionary payment settlements under the antitrust laws. In fact, the FTC, which has supervisory authority over the pharmaceutical industry, has challenged several of these settlement agreements as unreasonable restraints of trade. Some academic scholars also maintain that these agreements are presumptively illegal.

On the other hand, a number of courts have held that such settlement agreements, even though they result in the generic manufacturer's agreed exclusion from the market, are part of the exclusionary grant conferred by the branded manufacturer's patent, and therefore represent no more than the degree of exclusion lawfully provided for by the patent laws. The court that examined the issue in this case found that the settlement was a lawful exercise of patent rights. The Federal Circuit has agreed. *See In re Ciprofloxacin Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008). Moreover, the Second Circuit also has already agreed with this approach in *Joblove v. Barr Labs. Inc, (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187, 216 (2d Cir. 2005), often referred to as the *Tamoxifen* case.

In *Arkansas Carpenters Health*, a Second Circuit panel was confronted with whether to follow *Tamoxifen*. It did so but questioned and criticized *Tamoxifen* and, therefore, requested review of its decision by the entire Second Circuit through the *en banc* procedure.

2. The *Ciprofloxacin* Litigation

The Second Circuit opinion in *Arkansas Carpenters Health* involves the most prescribed antibiotic in the world, in which the active ingredient is ciprofloxacin hydrochloride or "Cipro." The Cipro patent was issued to Bayer in 1987 and was scheduled to expire in 2003. In 1991, Barr sought to market generic Cipro and filed a pre-expiration challenge under the Hatch-Waxman Act. In response, Bayer sued Barr in the Southern District of New York for patent infringement. Other potential generic manufacturers of Cipro were also eventually named as defendants.

In January 1997, Bayer and the generic competitors settled the Hatch-Waxman litigation. For its side, Bayer agreed to make an immediate payment and then subsequent payments during much of the patent's lifetime. It also agreed to provide the generic manufacturers a guaranteed license to sell brand-name Cipro at a reduced rate for six months prior to the patent's expiration. The generic competitors, in return, conceded the patent's validity and agreed not to market generic Cipro before the patent expired.

Three years later, Cipro purchasers instituted various antitrust lawsuits challenging the settlements that were consolidated in the Eastern District of New York. The allegations centered on the claim that the settlements exceeded the scope of Bayer's patent rights, based on the payments by Bayer to the generic manufacturers not to challenge the patent. The district court granted summary judgment for the defendants, reasoning that "[i]t goes without saying that patents have adverse effects on competition. However, any adverse effects within the scope of a patent cannot be redressed by antitrust law." *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 548 (E.D.N.Y. 2005).

Plaintiffs then appealed to the Second Circuit, questioning the validity of reverse exclusionary payment settlements.

3. *Tamoxifen*

In deciding plaintiffs' appeal, the Second Circuit panel declared itself constrained by *Tamoxifen*. In *Tamoxifen*, the Second Circuit upheld a motion to dismiss a challenge to a reverse exclusionary settlement payment, holding that "[u]nless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." *Tamoxifen*, 466 F.3d at 213.

Based on *Tamoxifen*, the Second Circuit panel in *Arkansas Carpenters Health* noted that plaintiffs' claims were neither those of sham litigation nor of a patent procured by fraud. Consequently, the only way around *Tamoxifen* would be if the plaintiffs showed that the settlement payment exceeded the scope of the Cipro patent. The panel reasoned that plaintiffs could not make the required showing because Bayer's Cipro patent was a "compound patent," meaning that, unlike a "formulation patent," all generic versions of the drug were covered. As a result, the panel determined that the agreement to refrain from manufacturing generic Cipro was in fact limited to infringing conduct, and, therefore, was within the scope of the patent rights. Plaintiffs made other arguments in an attempt to distinguish the case from *Tamoxifen*, none of which were availing to the Second Circuit panel.

Despite its determination that it had no choice but to be bound by *Tamoxifen*, the Second Circuit panel invited *en banc* review of the case.

4. The Reasons for *en banc* Review

The *Arkansas Carpenters Health* panel identified four reasons for *en banc* review:

- The United States Department of Justice has urged repudiation of *Tamoxifen* on grounds that it effectively precludes antitrust scrutiny of a private contract;
- Evidence shows that, since *Tamoxifen* was decided, there has been significantly increased settlement activity. In fact, the court cited statistics showing that before *Tamoxifen*, there were no reverse settlement payments in Hatch-Waxman Act cases as compared with twenty-seven such settlements after the decision was issued;
- Senator Hatch, one of the drafters of the Hatch-Waxman Act, has criticized reverse settlement payments, stating: "I find these types of reverse payment collusive arrangements appalling." Representative Waxman, the other drafter, opposes the practice as well;
- *Tamoxifen* mischaracterized the Hatch-Waxman Act. According to the Second Circuit panel, *Tamoxifen* was based on a belief that a 180-day exclusivity period granted the first-filed generic manufacturer would be available to later-filed manufacturers. The panel described that belief as "erroneous."

Finally, the Second Circuit panel encouraged *en banc* review because *Tamoxifen* was decided on a motion to dismiss for failure to state a claim before there had been any discovery in the case. In contrast, the current case was decided on appeal of a summary judgment determination made after discovery. Thus, the panel declared: "This case could provide our full court with an opportunity to revisit the issues in play in *Tamoxifen* and to analyze the competing interests that underlie antitrust challenges to reverse payment settlements in light of the full record and the arguments of the parties and amici, including the United States that have been raised in the appeal."

5. Possible Supreme Court Review

If the Second Circuit sitting *en banc* were to reverse the panel and subject reverse exclusionary settlement payments to antitrust scrutiny, there would be a split among different federal courts of appeals on this issue, which would provide a strong basis for Supreme Court review. We will continue to monitor additional review by the Second Circuit of this case and additional decisions on reverse exclusionary settlement payments and will update you accordingly.

The *Arkansas Carpenters Health* opinion is available here.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.