THE ELEVENTH CIRCUIT AND THIRD CIRCUIT DIVERGE ON REVERSE-PAYMENT SETTLEMENTS

Two recent courts of appeals decisions, the Eleventh Circuit’s Federal Trade Commission v. Watson Pharmaceuticals, Inc.1 (the “AndroGel” decision) and the Third Circuit’s In re K-Dur Antitrust Litigation,2 applied significantly different legal standards to reverse-payment settlements. In dismissing the Federal Trade Commission’s (the “FTC”) position that the lawfulness of a reverse-payment settlement depends on the perceived strength or weakness of the patent, the Eleventh Circuit concluded that a patent, unless previously invalidated, should be given its full exclusionary scope. In contrast, the Third Circuit rejected the “scope-of-the-patent” analysis, holding instead that reverse-payment settlements constitute “prima facie evidence of an unreasonable restraint of trade.”

The Eleventh Circuit Rejected The “Strength” Of The Patent As A Criterion For Settlement Legality And Reaffirmed The Scope-Of-The-Patent Test

The AndroGel case involved the settlement of a patent infringement suit between Solvay Pharmaceuticals, Inc. (“Solvay”), the holder of a patent for a brand-name drug called AndroGel, and generic producers of AndroGel. The settlement agreements allegedly included, among other terms, “reverse” payments by the patent holder, Solvay, to the asserted infringers, the generic producers. The settlements also included commitments by the generic manufacturers not to market generic AndroGel until 2015, five years prior to the expiration of the Solvay patent.

The FTC filed an antitrust complaint against parties to the settlement agreement alleging that the settlements were “unlawful agreements not to compete in violation of Section 5(a) of the Federal Trade Commission Act.” The FTC claimed that the generic challengers had “developed persuasive arguments and amassed substantial evidence that their generic products did not infringe the [ ] patent and that the patent was invalid and/or unenforceable.” The FTC argued that “because the [ ] patent ‘was unlikely to prevent generic entry,’ Solvay’s reverse payments to the generic drug producers continued and extended a monopoly that the patent laws did not authorize.”

The district court dismissed the FTC’s complaint, finding that Solvay had the right to exclude others to the full extent of the scope of its patent. On appeal, the Eleventh Circuit rejected the FTC’s reasoning that the lawfulness of a settlement depends on the perceived strength or weakness of the patent and affirmed the dismissal of the complaint.

The Eleventh Circuit “decline[d] the FTC’s invitation” to weigh the likelihood that the patent would have “blocked generic entry earlier than the agreed-upon entry date.” Rather, the Eleventh Circuit found the likelihood of Solvay’s success in the underlying patent litigation to be legally irrelevant because “[o]ne side or the other almost always has a better chance of prevailing, but a chance is only a chance, not a certainty.”

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1 677 F.3d 1298 (11th Cir. 2012).
The court explained that Eleventh Circuit precedent “focus[es] on the potential exclusionary effect of the patent, not the likely exclusionary effect.” A patent has the potential to exclude competition at settlement if it has not expired and has not been declared invalid by a court. The actual exclusionary power of the patent is irrelevant if judged after the settlement takes effect.

The court cited other reasons to reject the FTC’s “likely-to-prevail” approach. For example, the FTC’s reasoning would “require an after-the-fact calculation of how ‘likely’ a patent holder was to succeed in a settled lawsuit if it had not been settled.” Yet predicting the outcome of any litigation is speculative and cannot serve as a rule of law.

The Second Circuit and the Federal Circuit have also adopted the scope-of-the-patent legal standard for assessing reverse-payment settlements.

**The Third Circuit Rejected The Scope-Of-The Patent Test And Held That Reverse-Payment Settlements Are Presumptively Unlawful**

In the *K-Dur* potassium medication case, the Third Circuit rejected the scope-of-the-patent legal standard and adopted an alternative “quick look” standard advocated by the private plaintiffs and the FTC. The Third Circuit did so even though the Eleventh Circuit had upheld the same settlement on review in a case brought by the FTC. At issue in *K-Dur* are reverse-payment settlements involving the patent holder, Schering-Plough Corporation, and generic manufacturers of the potassium drug, K-Dur. A class of private plaintiffs alleged that the settlements violated the antitrust laws.

The district court granted summary judgment for the defendants on the basis that the settlements were within the exclusionary scope of the patent. The Third Circuit Court of Appeals reversed the judgment of the district court and held that reverse payments in the pharmaceutical sector are “prima facie evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment: (1) was for a purpose other than delayed entry; or (2) offers some pro-competitive benefit.”

The Third Circuit rejected the scope-of-the-patent test, as it took “issue with the . . . test’s almost unrebutable presumption of patent validity” because “[m]any patents . . . are later found to be invalid or not infringed.” The court cited studies, including one conducted by the FTC, concluding that generic challengers of patents had a success rate of about 42% to 73%. According to the court, those statistics “add force to the likelihood . . . that reverse payments enable the holder of a patent that the holder knows is weak to buy its way out of both competition with the challenging competitor and possible invalidation of the patent.”

The court also found that “aspects of the Supreme Court’s general patent jurisprudence” favored antitrust scrutiny of reverse payments. In particular, the Third Circuit quoted a 1947 Supreme Court decision for the proposition that there is a “broad public interest in freeing our competitive economy from the trade restraints which might be imposed by price-fixing agreements stemming from narrow or invalid patents.” The Third Circuit found the precedent relevant because “reverse payments permit the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid.”
The Third Circuit addressed public policy arguments as well. It explained that the scope-of-the-patent test undermined the regulatory framework of the Hatch-Waxman Act, which encourages generic manufacturers to challenge weak patents. Finally, the court acknowledged and dismissed arguments based on the judicial policy of enforcing settlement agreements: “[T]he judicial preference for settlement, while generally laudable, should not displace countervailing public policy objectives or, in this case, Congress’s determination . . . that litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers.”

The Third Circuit adopted a “quick look” rule-of-reason analysis. The court held that “the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as prima facie evidence of an unreasonable restraint of trade.” Patent holders can rebut the presumption of unlawfulness by proving that the payment was not for delay or that the payment “offers a competitive benefit that could not have been achieved in the absence of a reverse payment.”

**Implications**

The conflict on the legal standards applied by the Third Circuit and the Eleventh Circuit (and with the Eleventh Circuit, the Second and the Federal Circuits) increases substantially the likelihood that the legality of reverse-payment settlements will be definitively resolved by the Supreme Court. In the meantime, the FTC continues to review new pharmaceutical settlements pursuant to the Medicare Modernization Act and firmly holds its position against reverse-payment settlements.