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The Supreme Court Heightens Antitrust Scrutiny For ANDA Reverse Payment Agreements Between Pharmaceutical Companies

The U.S. Supreme Court yesterday ruled on the long-awaited *FTC v. Actavis* case concerning ANDA reverse payments, resolving a sharp circuit split. The Court held that settlement agreements that include reverse payments to end litigation between brand pharmaceutical companies and generic challengers must be evaluated under a "rule of reason" analysis to determine whether they violate federal antitrust laws. The decision could open the door for more government and private antitrust suits against pharmaceutical companies, both brand and generic, when they enter into reverse payment agreements.¹

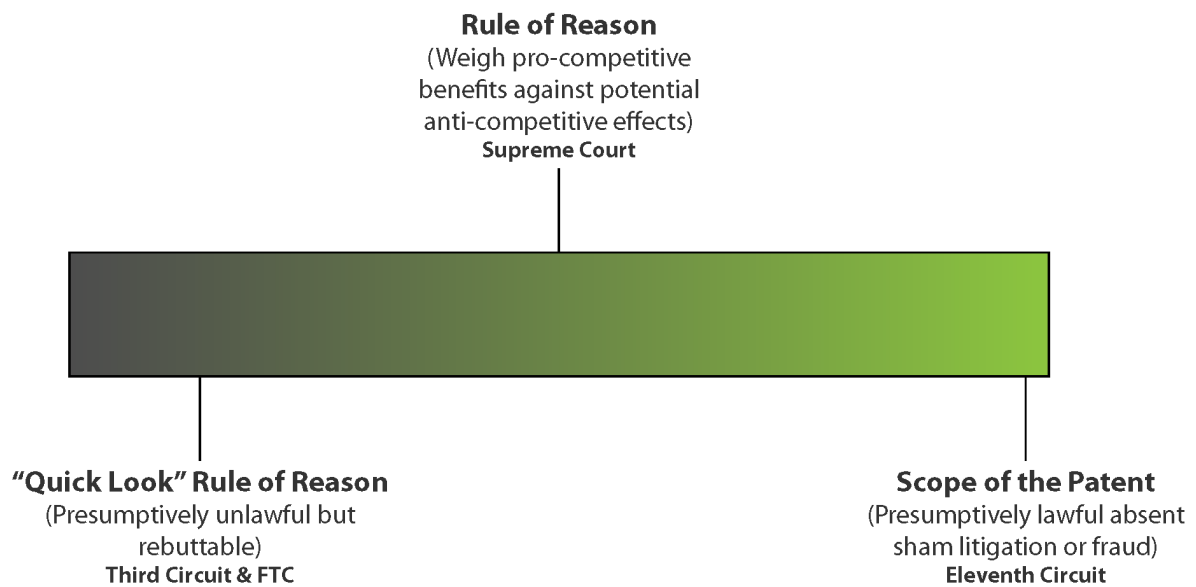
Whereas in typical patent litigation settlements the alleged infringer pays a royalty to the patentee, in Hatch-Waxman cases the payments are from the patentee (brand) to the alleged infringer (generic) with an agreement that the generic will forestall market entry for a specified period of time. Hence the name, "reverse payments." There was a split among various circuit courts on how to evaluate the legality of these arrangements, most recently between the Eleventh and Third circuits. The Eleventh Circuit, along with the Second and Federal Circuit courts,² applied a lenient "scope of the patent" test, where the reverse payment is presumptively legal absent a showing of sham litigation or fraud in obtaining the patent and so long as any anticompetitive effects fall within the scope of the exclusionary potential of the patent. To be unlawful under this test, an agreement would have to extend beyond a patent's expiration or somehow restrict competition for products or services unrelated to the patent. In contrast, the Third Circuit, along with the Sixth and D.C. Circuit courts,³ applied a stricter "quick look rule of reason" test. Under this test, there is a rebuttable presumption that any reverse payment is an unreasonable restraint on trade, which can be overcome only by a showing that the payment (1) was for a purpose other than to delay entry or (2) offers some pro-competitive benefit.

The Supreme Court's *Actavis* decision rejects both approaches, instead applying a standard that falls in the middle. While not finding them presumptively illegal, as the FTC argued, the Court explained that such agreements should be evaluated under a "rule of reason" test that weighs their pro-competitive benefits against their potential harm to competition.

1 *FTC v. Actavis, Inc.*, No. 12-416 (June 17, 2013).

2 See *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1323 (11th Cir.2012), *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir.2006), and *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008).

3 See *In re K-Dur Antitrust Litigation*, 686 F.3d 197, 218 (3d Cir.2012), See also *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir.2003), *Andrx Pharmaceuticals, Inc. v. Biovail Corp. International*, 256 F.3d 799 (D.C. Cir.2011).



Under the rule of reason test, the FTC or private plaintiffs bear the initial burden to prove the challenged action has an *actual* adverse effect on competition as a whole. If so, then the burden shifts to the defendant to establish a pro-competitive redeeming value. At which point the burden shifts back to the plaintiff to show that the same pro-competitive effect could have been achieved through less restrictive means.

With these general guidelines, the Court directed the lower courts to structure the exact rule of reason to be used in this type of antitrust analysis. But it did indicate that such factors as the reverse payment size, scale in relation to the payer's anticipated future litigation costs, independence from other services for which it might represent payment, and the lack of any other convincing justification will all dictate the likelihood of finding of anticompetitive effects.

The result of this landmark decision is that reverse payments are no longer shielded by the exclusionary power of the scope of the patent and transactions will be scrutinized much more closely. Practically, this means that settling companies must ensure that payments and agreements are justified with economic metrics balanced against the strength of the patent. But the ultimate burden will rest with the FTC (or private plaintiffs) to prove that the agreements actually harm competition.

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