

INSIGHTS

High Court Finds Antitrust Scrutiny Applies to Pay-for-Delay Settlements

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On June 17, 2013, the U.S. Supreme Court determined that the Federal Trade Commission's (FTC) antitrust challenge to a reverse payment settlement agreement between drug manufacturers, otherwise known as a "pay-for-delay" deal, may go forward, reversing the Eleventh Circuit's dismissal of the FTC's complaint.¹ In a 5-3 decision, the majority of the Court found that these forms of settlement, whereby a branded pharmaceutical manufacturer that owns a drug patent pays a generic manufacturer some amount of money (often a large sum) to delay market entry, are "unusual," and could have a significant adverse effect on competition. Thus, the Court held that pay-for-delay agreements should be reviewed using a "rule of reason" analysis that weighs the pro-competitive benefits of the settlement against its potential anticompetitive effects.² The Eleventh Circuit previously had found that the pay-for-delay agreement at issue between Solvay Pharmaceuticals, Actavis, and others was immune from antitrust scrutiny because its anticompetitive effects fell within the scope of the patent's exclusionary potential, as it did not extend the subject matter or term of the patent.³ The Circuit Court noted in its decision the general legal policy favoring the settlement of disputes and that courts could not require parties to continue to litigate in order to escape antitrust liability.

In reversing the Eleventh Circuit, the Supreme Court stated that patent law does not immunize reverse settlement agreements from antitrust attack. Justice Breyer, writing for the majority, explained that in pay-for-delay cases, because it is not known whether a patent is valid or whether it has been infringed, it therefore "would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy[...]"⁴ Instead, the majority concluded, both patent law policy and antitrust law policy are relevant in determining the scope of monopoly power and antitrust immunity conferred by a patent, and the antitrust question should be answered by examining traditional antitrust factors.

Although the Court acknowledged the general legal policy of favoring the settlement of disputes, particularly in complex cases, it was not persuaded that this should prohibit antitrust scrutiny in pay-for-delay cases, for several reasons. Delayed market entry by a cheaper generic version of a drug has the potential for "genuine adverse effects on competition," and, at least in some cases, the anticompetitive effects cannot be justified. Additionally, it normally should not be necessary to litigate patent validity to answer the antitrust question, and in particular, a large unexplained reverse payment can provide a proxy for a patent's weakness. Parties also

would not be prevented from settling patent disputes in other ways.

The FTC did not win the pay-for-delay battle on all fronts, as the Court declined to hold that reverse settlement payments are presumptively unlawful, despite the FTC urging it to do so. Rather, the Court found the “rule of reason” approach to be more appropriate, because the likelihood of a reverse payment having an anticompetitive effect is not clear-cut and depends on several factors, such as “its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”⁵ The Court, therefore, acknowledged that legitimate justifications may exist for reverse payments.

In his dissent, Chief Justice Roberts noted the purpose of patent law is to grant limited monopolies in order to promote innovation and explained that the correct question to ask is whether the settlement gives the patentee monopoly power beyond what the patent already conferred on it. The Chief Justice warned that the majority’s decision will discourage settlements of patent litigation and may also discourage generic manufacturers from challenging a branded company’s patent in the first place, due to the uncertainty regarding available settlement options.

The Supreme Court’s decision likely will make it harder for drug companies to get pay-for-delay lawsuits dismissed at the early stages of litigation and may open the floodgates to more challenges of such patent settlements. The Supreme Court’s opinion does provide some guidance regarding the factors to be considered in determining a reverse payment’s validity, but the lower courts will need to sort out the details with respect to specific settlements, setting the stage for varied and potentially conflicting decisions by different courts.

Additionally, the decision likely will cause drug companies to structure patent settlements differently and focus more heavily on the size of reverse payments and their justifications, although it remains to be seen whether the Court’s ruling will result in fewer settlements in drug patent cases, as the dissent predicts.

¹ [*Federal Trade Comm’n v. Actavis Inc.*](#), No. 12-416, 570 U.S. ____ , (2013) WL 2922122 (June 17, 2013).

² *Federal Trade Comm’n v. Actavis Inc.*, No. 12-416, 570 U.S. ____ , (2013) WL 2922122, at *2, 13-14 (June 17, 2013).

³ [*Federal Trade Comm’n v. Watson Pharm., Inc.*](#), 677 F.3d 1298, 1312 (11th Cir. 2012), *rev’d sub nom. Federal Trade Comm’n v. Actavis, Inc.*, No. 12-416, 570 U.S. ____ , (2013) WL 2922122 (June 17, 2013).

⁴ *Actavis*, 2013 WL 2922122, at *1.

⁵ *Id.* at *13.