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Supreme Court Holds Reverse Payment Settlements Are Subject to Rule-of-Reason Scrutiny in Landmark Ruling

June 21, 2013

In *Federal Trade Commission v. Actavis, Inc.*, the Supreme Court, in a 5-3 decision written by Justice Breyer, reversed the Eleventh Circuit's dismissal of an FTC complaint under Section 5 of the Federal Trade Commission Act[1] challenging a pharmaceutical reverse payment settlement even though the exclusionary effect of the settlement was within the scope of the patent grant. Although the Court rejected the "rule of presumptive illegality" advocated by the FTC and held that the FTC "must prove its case as in other rule-of-reason cases,"[2] the decision upends the prevailing Circuit Court view that the anticompetitive effects of settlement pursuant to Hatch-Waxman litigation are assessed by reference to the scope of the challenged patent.[3] While the ruling resolves the Circuit split created by last year's Third Circuit decision in *In re K-Dur Antitrust Litigation*,[4] it dramatically alters the certainty implicit in, and the incentives for settlement of, patent infringement litigation between brand-name and generic pharmaceutical manufacturers.

The FTC's challenge in *Actavis* focused on Solvay Pharmaceuticals' settlement agreement with several generic pharmaceutical patent challengers following Hatch-Waxman Act (the "Act") litigation involving Solvay's AndroGel®. In 2003, Solvay obtained a patent for AndroGel, a prescription testosterone treatment. Later that year, Actavis (formerly Watson Pharmaceuticals) filed an Abbreviated New Drug Application ("ANDA") under the Act for a generic version of AndroGel, which certified that Actavis' patent was invalid.[5] Shortly thereafter, Paddock Laboratories also filed an ANDA with a similar certification.[6] Solvay, in turn, commenced litigation against Actavis and Paddock alleging patent infringement, resulting in a mandatory 30-month stay of the ANDA approval process pursuant to the Act.[7] In 2006, the parties reached a settlement with Actavis agreeing not to bring their generic product to market until 2015, 65 months before the AndroGel patent expired, and Solvay agreeing to pay $12 million to Paddock and $19-30 million annually to Actavis for nine years.[8]

In early 2009, the FTC filed suit against Solvay as well as its generic challengers alleging that the settlement agreement violated Section 5 of the Federal Trade Commission Act. The FTC alleged that the parties unlawfully agreed to share the monopoly profits to be derived from Solvay's patent in exchange for delaying the introduction of generic competitors that would benefit consumers through lower prices.[9] Like the District Court, the Eleventh Circuit rejected the FTC's challenge, holding that, absent sham litigation or fraud in obtaining the patent, reverse payments are immune from antitrust attack so long as their anticompetitive effects fall within the exclusionary potential (*i.e.,* temporal duration) of the patent.[10]

Rejecting the Eleventh Circuit's view that patent law controls the inquiry, the Supreme Court's decision in *Actavis* holds that reverse payments are subject to rule-of-reason analysis that "consider[s] traditional antitrust factors such as likely anticompetitive effects, redeeming virtues [*i.e.*, procompetitive effects], market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents."[11] The Court explained that rule-of-reason analysis is appropriate because reverse payments have "the potential for genuine adverse effects on competition," particularly when they involve ANDA first filers and "remove[] from consideration the most motivated [generic] challenger."[12] Contrary to the Eleventh Circuit's understanding, antitrust review of reverse payments does not require an unwieldy assessment of patent validity because large reverse payments may serve as a surrogate for a patent's weakness, whereas settlement remains an option in absence of such payments.[13]

In a vigorous dissent, Chief Justice Roberts assailed the majority for, in his view, a misreading of Supreme Court precedent. The Chief Justice pointed out that a patent grant "provides an exception to antitrust law, and the scope of the patent – *i.e.*, the rights conferred by the patent – forms the zone within which the patent holder may operate without facing antitrust liability."[14] Responding to the majority's contention that a reverse payment settlement draws into question a patent's validity and, thus, antitrust immunity, the dissent countered that questions of patent validity must be resolved through resort to patent principles and not antitrust law.[15]

Although the Supreme Court's decision resolves the Circuit split created by the Third Circuit's decision in *In re K-Dur Antitrust Litigation*, the contours of reverse payment rule-of-reason analysis remain undefined. Indeed, the Court's decision acknowledges that the lower courts must fill in the structure of the investigation. Furthermore, it remains to be seen whether the application of rule-of-reason analysis will discourage settlements under the Act or discourage generics from challenging pharmaceutical patents in the first instance. It is now clear, however, that Hatch-Waxman litigation settlements are subject to thorough review and, consequently, that the incentives for both brand-name and generic pharmaceutical manufacturers to settle have been altered.

Related Precedent-setting Decision by European Commission in *Lundbeck*

Two days following the Supreme Court's decision in *Actavis*, the European Commission released its opinion in *Lundbeck*, a precedent-settingdecision imposing monetary sanctions in one of the Commission's first cases dealing with reverse payments. The Commission fined Lundbeck, the Danish developer of the antidepressant Citalopram, € 93 million, and its generic rivals, Alpharma, Ranbaxy and others, a total of € 52 million. Although the patent protecting Citalopram's active ingredient expired in 2002, Lundbeck possessed patents which protected the drug's manufacturing processes. In order to forego a challenge to these patents, Lundbeck entered agreements which compensated its generic rivals to remain off the market prior to the patents' expiration. The Commission's decision found the arrangements to be anticompetitive agreements in violation of Article 101 on the Treaty on the Functioning of the European Union.

[1] 15 U.S.C. § 45.

[2] *FTC v. Actavis, Inc.*, 2013 WL 2922122 at *13 (June 17, 2013).

[3] See *In re Ciprofloxacin Hydrochloride Antitrust Litig.,* 544 F.3d 1323 (Fed. Cir. 2008) (applying scope of the patent test); *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) (same); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (same); contra *In re K-Dur Antitrust Litig*., 686 F.3d 197, 209 (3d Cir. 2012) (applying "quick look" rule of reason analysis).

[4] *In re K-Dur Antitrust Litig*., 686 F.3d 197 (3d Cir. 2012).

[5] Under the Hatch-Waxman Act, the first ANDA filer is entitled to 180 days of generic marketing exclusivity which is the period of greatest generic profits.

[6] Although it did not file an ANDA, generic manufacturer Par Pharmaceutical entered into an agreement with Paddock in which it agreed to share patent litigation expenses in exchange for a share of Par's profits if Par obtained FDA approval of its ANDA.

[7] 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A) (paragraph IV certification constitutes a constructive act of patent infringement); 21 U.S.C. § 355(j)(5)(B)(iii).

[8] Solvay additionally agreed to pay $60 million to Par.

[9] *FTC v. Watson Pharms., Inc*., 677 F.3d 1298, 1305-06 (11th Cir.), cert. granted, 133 S. Ct. 787 (2012), rev'd sub nom. *FTC v. Actavis, Inc.*, 2013 WL 2922122 (June 17, 2013).

[10] *Id.*at 1312.

[11] *Actavis*, 2013 WL 2922122, at *7.

[12] *Id.* at *10-*11 (citations omitted).

[13] *Id.*at *12.

[14] *Id.*at *14.

[15] *Id.*at *19.