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Client Alert

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Applying the Supreme Court's Decision in *Actavis*

Consideration Value Comparisons by Courts Approving Reverse Payment Settlements

In *FTC v. Actavis*, the Supreme Court held that "reverse payment" pharma patent settlements within the scope of the patent may (or may not) violate the Sherman Act.[1] The majority opinion in *Actavis* explained that Hatch-Waxman infringement settlements that involve a flow of consideration from the patent holder/innovator to the alleged infringer/generic are not presumptively unlawful and should be analyzed under the Rule of Reason. This standard requires a trial court to weigh the settlement's possible pro-competitive benefits against its potential anticompetitive effects. Applying the Rule of Reason is often difficult in practice because the analysis requires a comprehensive review of the economics associated with the examined conduct or agreement. This is especially true in the reverse payment context, which involves settlement of high-stakes litigation and a mix of diverse incentives with murky competitive effects. Unfortunately, the Supreme Court did not offer specific guidance to lower courts and pharma companies addressing the complexities of analyzing reverse payment settlements under the Rule of Reason.

Below we offer an approach that brings the antitrust analysis under the purview of the court presiding over the patent litigation and suggests that the analysis be performed at the time of settlement. Further, we propose that given the unique incentives created by the Hatch-Waxman Act, the Rule of Reason analysis of such a settlement can be distilled to a comparison of the settlement consideration received by both the innovator and the generic. The procedure and calculus outlined here is meant to determine in an efficient manner whether the innovator is appropriately mitigating against an adverse decision on its patent or instead simply is "paying for delay" of generic competition.

The Statute

In 1984, Congress passed The Drug Price Competition and Patent Term Restoration Act commonly referred to as the "Hatch-Waxman Act."[2] The Hatch-Waxman Act created processes and incentives for both innovator and

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generic companies involving challenges to patents. The basic Hatch-Waxman framework is as follows:

- Innovators must list their patents in the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

- When applying to market a generic form of a branded drug, the generic files an Abbreviated New Drug Application (ANDA) with FDA and certifies against the innovator's patents listed in the Orange Book. The certification by the generic states that either: (a) FDA should approve its generic version after the date the last patent expires (a "Paragraph III" filing); or (b) that its generic product does not infringe on the listed patents or that those patents are invalid (a "Paragraph IV" filing).

- If the generic files an ANDA with a Paragraph IV certification, then the innovator is notified and has 45 days to file a patent infringement action against the generic. The Hatch-Waxman Act provides that filing a Paragraph IV certification constitutes actionable potential infringement even without other efforts toward commercialization. Because of this statutory feature, the generic is afforded the opportunity to litigate the patent legality of its product without risking a potential damage claim from the innovator.[3] After a suit is filed, FDA cannot approve the application until the generic successfully defends the suit or until 30 months, whichever comes first.

- If the first generic to file an ANDA wins the patent litigation, it may commercialize its product and enjoys a 180 period of exclusivity vis-à-vis other generics. The entry by a successful generic typically results in substantial revenue for the generic and a substantial decrease in revenue for the innovator.

Against this regulatory backdrop, reverse payment patent settlements essentially involve some form of consideration from the innovator (the patent holder) to the generic (the patent challenger/alleged infringer) in exchange for the resolution of the underlying Hatch-Waxman patent litigation. Typically, the generic agrees to refrain from using the patent and commercializing the allegedly infringing product for some defined period of time.

The Federal Trade Commission began challenging reverse payment settlements as violating Section 1 of the Sherman Act in the late 1990s. The FTC's position on reverse payments evolved from initially asserting that all reverse payment settlements are *per se* illegal to more recently taking the position that reverse payment settlements are presumptively unlawful and subject to a "Quick Look" review, a position shared with the Department of Justice Antitrust Division.[4] In challenging such agreements, the FTC had little success in the appellate courts. Since 2005, the Second, Eleventh, and Federal Circuits all held that reverse payment settlements do not violate the antitrust laws unless the exclusionary effects of the settlement exceed the scope of the patent at issue.[5] The Third Circuit, however, held that all reverse payment settlements that presumptively unlawful, and only the Sixth Circuit found a *per se* violation of the antitrust laws based on agreement to make reverse payments.[6]

The Supreme Court's Decision

In 1999, Solvay Pharmaceuticals filed a New Drug Application with FDA for its new drug, Androgel. Subsequently, Actavis (then known as Watson Pharmaceuticals) and Paddock Laboratories filed ANDAs with FDA for generic versions of Androgel.[7] Solvay initiated the resulting patent infringement litigation, and the parties settled in 2006.[8] In January 2009, the FTC filed suit against the settling parties alleging violation of Section 5 of the Federal Trade

Commission Act. The FTC claimed that by abandoning their patent challenges and refraining from entering the market as lower cost generic alternatives, the generics agreed to unlawfully share in Solvay's monopoly profits. The FTC contended that the reverse payment settlement violated antitrust laws because it contained large unexplained payments. The district court held that the actions did not constitute an antitrust violation and dismissed the action. On appeal, the Eleventh Circuit affirmed the district court, reasoning that a reverse settlement payment is "immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."[9]

On June 17, 2013, the Supreme Court in *FTC v. Actavis* reversed the Eleventh Circuit and held that reverse payment settlements could violate antitrust laws even if they were within the scope of the patent.[10] In a notable difference from recent antitrust decisions, the Court's opinion was supported by a bare majority.[11] The *Actavis* decision rejects the argument that settlements within the scope of a patent are "immunized" from the antitrust laws because of the monopoly given to the patent holder under the patent laws. Instead, the Court held that the conduct of a patent holder, even within the scope of a valid patent, must comport with antitrust principles.[12]

Importantly, the Court recognized that the innovator would have lost hundreds of millions of dollars if its patent had been found invalid or not infringed and as a result generic competition began prior to patent expiration.[13] The innovator agreed to pay the generic manufacturers a portion of those profits, potentially delaying the competition that would have followed a generic victory in the patent litigation. Nevertheless, the Court did not agree with the FTC that such reverse payments should be considered presumptively illegal and subject to a "Quick Look" analysis. Instead, the Court held that reverse payment settlements are neither immune from antitrust attack nor presumptively unlawful but instead are to be analyzed under the Rule of Reason.[14] The Court offered several factors to be considered in applying the Rule of Reason to such settlements: "[t]he likelihood of a reverse payment bringing about anticompetitive effects depends upon 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."[15] The *Actavis* decision does not specify to lower courts the weight properly given to factors such as the strength of the patent, the regulatory environment, the size of the settlement, or the extent of the delay.

Analyzing Reverse Payments at the Time of the Settlement

Actavis instructs lower courts, pharma companies, and the FTC to evaluate the individual characteristics of any reverse payment settlement to determine whether there is "pay for delay" and a likely antitrust violation. Our proposal suggests that this evaluation be done by the district court hearing the infringement action as part of a process for approving the settlement of the patent case. To ensure that a reverse payment does not reflect any payment solely for the delay of generic competition, the court should make an assessment of the economics of a proposed settlement by comparing the innovator's expected cost of losing the litigation and any other explained costs (*e.g.*, litigation costs) to the consideration received by the generic.

The consideration value comparison by the court presiding over the infringement claim could be made in connection with a hearing. Other options for the court conducting the consideration value comparison include: (a) employing a special master; (b) inviting the FTC to participate in the proceedings; and (c) utilizing some other proxy or procedure designed to represent the public interest. If the consideration received by the generic is determined to exceed the expected cost to the innovator should the generic win the patent case and enter the market, then the innovator is essentially paying the generic to delay entering the market, and the court should find the settlement invalid as contrary to the antitrust laws. On the other hand, if the consideration received by the generic is no more than the expected value

of the settlement to the innovator, then a court should find the agreement lawful under the antitrust laws and approve the settlement of the infringement suit.

The innovator's cost of losing the patent litigation should be determined by the lost profits of the innovator from generic competition mitigated by the litigation odds plus the innovator's expected litigation costs and any other explained costs. This value would represent the loss expected by the innovator in the litigation and the amount the innovator would reasonably pay to settle the case. Recognizing that such a valuation necessarily would be complex, calculation of the cost to the innovator of a loss in the infringement case could follow the following basic process:

- Determine the net present value of the innovator's future revenues until patent expiration;
- Determine the sales that would be lost to generic products if the innovator loses the patent litigation;
- Determine the likelihood of the innovator company losing the patent litigation; and
- Use these determinations to calculate the value of the settlement to the innovator.

By way of example, if (1) the innovator's future pre-patent expiration revenues had a net present value of $1 billion; (2) the innovator would lose 90% of its sales upon generic entry; [16] and (3) the innovator's probability of litigation success was 60% making its chance of losing 40%: then the value of a settlement to the innovator would be $360 million ($1 billion × 90% × 40%). If the innovator's expected legal and other explainable costs associated with conducting the litigation were $10 million, then total value of the settlement to the innovator would be $370 million. The court may also decide to enforce a threshold for the innovator's probability of success in the patent case. If the innovator's chances of obtaining a favorable infringement decision were minimal, then the court may choose to find that any payment from the innovator to the generic constitutes a "pay for delay" antitrust violation.[17] Lower courts also may decide to employ a "sliding scale" in setting a threshold for the probability of innovator's patent success.[18] If such a "sliding scale" is applied, then pharmaceuticals that compete with different molecules or other therapeutic alternatives ought to be afforded a lower threshold of probability of success for the innovator's infringement case.

On the other side of the equation, the value to the generic would be determined by the value of consideration received by the generic. Consideration components could include cash payments, litigation costs avoided, the value of supply, marketing, royalty, or license agreements (including those relating to other products), or any other form of value provided by the innovator, including agreeing to forego an authorized generic.

Conclusion

The suggestion outlined above provides an efficient method to assess reverse payment settlements in light of *Actavis.* By determining of antitrust legality before a reverse payment agreement becomes effective, a consideration value comparison by the court considering the infringement settlement provides innovator and generic pharma companies with additional incentive to settle and avoid the inefficient transaction costs associated with conducting patent litigation. Additionally, such an antitrust determination made by the same court presiding over the infringement claim promotes judicial efficiency by bringing the patent and antitrust determinations into a single forum.

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[1] *FTC v. Actavis, Inc*., 133 S.Ct. 2223, 570 U.S. ___ (2013).
[2] Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271), as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (collectively, the "Hatch-Waxman Act").
[3] Some commentators have criticized the term "reverse payments" as a misnomer because in a typical Hatch-Waxman patent suit the alleged patent infringer bears virtually no risk of paying monetary damages.
[4] In 2003, the FTC gained specific authority to review brand-generic settlement agreements implicating the 180-day exclusivity. Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (the "MMA"). Under the MMA, innovators and generics settling infringement cases are obligated to file the relevant agreements with the FTC within 10 days of execution. Consistent with its broader mandate to enforce the antitrust laws, the FTC may challenge any settlements that it believes violate the antitrust laws. *See* FTC MMA Statement, January 7, 2004 available at: http://www.ftc.gov/os/2004/01/040106pharmrules.pdf.
[5] *Ark. Carpenters Health and Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2005); *In re Ciproflaxin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1335 (Fed. Cir. 2008).
[6] *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012); *In re Cardizem CD antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003).
[7] Par Pharmaceuticals, a respondent, did not file an ANDA, but agreed to work with Paddock Laboratories and shared in the litigation expenses. 133 S.Ct. at 2229.
[8] Pursuant to the settlement agreement, Actavis agreed not to enter the market until August 31, 2015 which was sixty-five months before Solvay's patent was set to expire. Additionally, Actavis agreed to promote Androgel to urologists in the meantime. Paddock and Par Pharmaceuticals also reached similar deals. In return, Solvay agreed to pay $12 million to Paddock, a $60 million to Par Pharmaceuticals, and up to $270 million to Actavis. *Id*.
[9] *FTC v. Watson Pharms., Inc*., 677 F.3d 1298, 1312 (11th Cir. 2012).
[10] 133 S.Ct. at 2234.
[11] The Court unanimously decided both *American Needle v. National Football League*, 130 S.Ct. 2201 (2010) and *FTC v. Phoebe Putney Health Sys.*, 133 S.Ct. 133, 568 U.S. ___ (2013). *Actavis* is 5-3 decision with Justice Breyer writing the majority opinion joined by Justices Kennedy, Ginsburg, Sotomayor, and Kagan, and the Chief Justice filing a dissenting opinion in which Justices Scalia and Thomas joined (Justice Alito did not participate).
[12] 133 S.Ct. at 2234.
[13] *Id.*
[14] *Id.*
[15] *Id*. at 2237.
[16] FTC studies estimate that innovator companies lose on average 90% of their sales upon generic entry. *See* http://ftc.gov/os/2010/01/100112payfordelayrpt.pdf.
[17] In the circumstance where the innovator has absolutely no chance of winning the patent case, the innovator may have antitrust liability simply for asserting a "sham" infringement claim. *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993).
[18] 133 S.Ct. at 2235-37.