

FTC v. Actavis, Inc. Q&A: Implications for Pharmaceutical Companies

On June 17, 2013, in *FTC v. Actavis, Inc.*,¹ the U.S. Supreme Court ruled that plaintiffs may bring antitrust suits against so-called “reverse payment” or “pay-for-delay” settlements, under which pioneer and generic pharmaceutical companies resolve patent disputes through arrangements that involve the transfer of cash or other consideration from the patent owner to the alleged infringer.² The case, however, also left many unanswered questions for companies that are contemplating or have entered into settlements that could be viewed as falling within these categories. These companies may want to consider the following questions, among others:

Does the Court’s rejection of the FTC’s “presumptive illegality” test matter from a counseling perspective?

The Court rejected the “scope-of-the-patent test,” under which the U.S. Courts of Appeals for the Second, Eleventh, and Federal Circuits had held that companies involved in such patent settlements were immune from antitrust liability if the settlements did not restrict competition to a greater degree than the patent would have if valid and infringed. The Court, however, also rejected the FTC’s “presumptive illegality” test. This rejection may matter a great deal for antitrust litigation because the opportunity to contest anticompetitive effect opens up a whole area of discovery, opposition to partial summary judgment, and trial, but it may not matter for counseling purposes. The Court says that an antitrust plaintiff cannot simply leap over the question of anticompetitive effect and go immediately to the defendants’ pro-competitive justifications, but the Court also says that lower courts are free to use a “sliding scale” to determine whether there is enough of an inference of anticompetitive effect to warrant exploring the defendants’ justifications. As a counselor, one has no idea in what forum an antitrust case might end up or what standards the judge will require the plaintiff to satisfy in order to meet its initial burden. Accordingly, a prudent counselor would immediately start by questioning the business people about why they felt it was necessary to venture into territory that carries antitrust risk. In other words, a counselor would go directly to the question of justification, just as he or she would have if the Court had accepted the FTC’s “presumptive illegality” test.

Will companies have to venture outside the safe harbor?

The Court, echoing the government, virtually made it a safe harbor to settle a patent case “by allowing the generic manufacturer to enter the patentee’s market before the patent expires without the patentee’s paying the challenger to stay out prior to that point.” It also made clear that it was safe to pay a nuisance payment representing saved litigation costs. Therefore, for patent cases that have not yet settled, many companies may choose to stay safely within those lines. For both sides, that may make the choices starker and the bargaining harder. A patent holder with a very strong patent on a blockbuster product may not be willing to tolerate even a very small risk of losing the patent litigation. On the other hand, a generic company in that situation may find it hard to pass up a few hundred million dollars in the form of entry a few years before patent expiration, even if there is a chance that going to trial might

1. *FTC v. Actavis, Inc.*, No. 12-416 (U.S. June 17, 2013), available at http://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf.

2. Willard K. Tom, one of the authors of this piece, was general counsel of the FTC at the time the FTC filed its petition for certiorari. This analysis relies only on public information and does not purport to represent the views of the FTC or any of its Commissioners.

produce earlier entry. This is especially true because so much of the first ANDA filer's profits come during the 180-day exclusivity period, whether that period comes earlier or later. The Court's decision makes the settlement of patent litigation much less like "Getting-To-Yes" win-win negotiation and much more like high-stakes poker.

If companies might have to venture outside the safe harbor, what issues should they consider?

If companies think they may not be able to stay within the safe harbor, there are some strategic and tactical considerations to which they may have to pay closer attention. What documents are the business people creating as they assess the prospects and risks of patent litigation? If they are privileged documents, are they taking the proper steps to maintain the privilege? Will they want to waive that privilege at some point in the future? Should the antitrust law of a particular circuit court be taken into account when choosing where to file the patent litigation, on the theory that the venue of the **patent** litigation might provide a basis to transfer a future antitrust case? If unrelated business transactions are being entered into between the same parties in the same time frame as the patent settlement, how will they be able to prove that only fair market value was exchanged? Can they adopt "clean room" procedures to reduce the chances that a future antitrust plaintiff can challenge the valuation of the other business transactions, alleging that the transactions are actually a disguised payment for delay? Given that the FTC has already expressed that a promise by an NDA holder not to launch an authorized generic during the first ANDA filer's exclusivity period represents compensation to the ANDA filer, should such terms be avoided?

What will happen to existing settlements of patent cases?

For patent cases that have already settled, things will get even more interesting. We can expect many challenges to agreements that have not yet been the subject of antitrust litigation. But even old antitrust cases that were decided in favor of the settling parties may now be resurrected by other parties who were not part of the previous litigation and therefore may not be barred by *res judicata* and collateral estoppel. Where will those challenges be brought? Will the FTC return to the administrative forum? Will it, and private plaintiffs, seek out circuits where the law on the rule of reason is fairly favorable to plaintiffs? In private damage actions, even if it is not necessary to litigate patent validity to determine antitrust **liability**, can a plaintiff prove **damages** without showing what would have happened in the absence of the settlement? Are these cases analogous to those subject to the filed rate doctrine, whereby a regulatory scheme that does not prevent an antitrust injunction nonetheless precludes damages?

What impact will the decision have on efforts to obtain legislation in this area?

Conceivably, PhRMA and GPhA could press for legislation to overrule the Supreme Court's decision and enact the "scope of the patent" test. But such an effort would have unclear prospects for success, raising questions about whether it would be worth the expenditure of time and resources to pursue such legislation.

What implications does the decision have for settlements concerning biosimilars?

Certainly, the statutory scheme for expedited approval of biosimilars is quite different from the Hatch-Waxman Act, and the Supreme Court seemed to think that the peculiarities of the Hatch-Waxman Act played a large role in generating "reverse payment" settlements. Those peculiarities are absent from the laws governing the approval of generic drugs in Europe, yet the European Commission has found and pursued instances of what it believes to be "reverse payment" settlements. If such settlements are found in this country with respect to biosimilars, is it likely that the lower courts would apply a standard similar to that endorsed by the Supreme Court in *Actavis*, notwithstanding the distinct statutory schemes and factual circumstances?

We hope you found this Q&A useful. If you have further questions in this area, please feel free to contact Will Tom at wtom@morganlewis.com or 202.739.5389, Scott Stempel at sstempel@morganlewis.com or 202.739.5211, or Steve Reed at sreed@morganlewis.com or 215.963.5603.