On March 25, 2013, the Supreme Court of the United States heard argument on the issue of pharmaceutical patent settlement agreements between branded and generic drug companies that contain so-called “pay-for-delay” or “reverse payment” provisions. Federal Trade Commission v. Actavis, Inc., involves the Federal Trade Commission’s (FTC’s) appeal of the U.S. Court of Appeals for the 11th Circuit’s order affirming dismissal of an FTC charge that such an agreement was an unfair method of competition in violation of Section 5 of the Federal Trade Commission Act. Proof that an agreement between competitors is anticompetitive under Section 5 (which only the FTC may enforce) and under Section 1 of the Sherman Act (for which there is a private right of action) is essentially the same. The Supreme Court’s ruling in FTC v. Actavis will almost certainly have major implications for the viability of FTC and private suits alleging that pay-for-delay settlements are anticompetitive, and for the level of antitrust risk facing companies that enter into such settlements.

Pay-for-delay challenges arise from settlements of patent infringement suits by branded drug patent holders against generic drug applicants under the Hatch-Waxman framework. Two provisions must be present for the theory to apply: a restriction on generic entry until a future date (even if the entry precedes patent expiration), and payment of money or other value by the brand to the generic firm. The payment typically is part of an ancillary agreement, such as a supply or co-promotion arrangement or IP license (coined a reverse payment because the plaintiff pays the defendant to settle). The FTC argues that this paradigm delays competition because it likely induces the generic to settle for later entry, or would have under exclusivity provisions if it won the lawsuit. The FTC finds the agreements presumptively unlawful and would put the burden on defendants to prove otherwise. Defendants counter that the patent conveys a right to exclude and that these settlements promote and accelerate competition, because they enable generic entry prior to patent expiration. Defendants assert that the burden should remain with the plaintiff to prove an anticompetitive effect.

The facts alleged in the FTC complaint squarely fit this paradigm. The settlement occurred in 2006. Solvay marketed branded drug Androgel. A formulation patent claiming Androgel expires in 2020. Generic drug firm Watson (now Actavis) had applied to the U.S. Food and Drug Administration for approval to launch a generic version of Androgel and certified that the generic product did not infringe Solvay’s patent and that the patent was invalid. Solvay sued Watson and another firm for patent infringement, then settled. The parties agreed that Watson would not launch its generic version of Androgel until 2015—five years prior to patent expiration—and Watson would promote Androgel to a key customer source, urologists, and be compensated by Solvay for those services. The agreement thus contains both components of an FTC pay-for-delay paradigm: a time-restriction on generic entry and a reverse payment.

The 11th Circuit followed its own precedent in rejecting the FTC case under the “scope-of-the-patent” test. (The Second and Federal Circuits apply the same test.) Under that analysis, if the patent was not obtained by fraud, and the infringement suit is not a sham (i.e., objectively baseless), then a settlement does not violate the antitrust laws if its terms do not expand the exclusionary scope of the patent, such as by prohibiting generic entry even after the patent expires. Since the Solvay-Watson settlement provided for generic entry five years earlier than that date, it failed that test. The 11th Circuit also rejected the FTC’s argument that pay-for-delay settlements are not reasonable because they delay competition.

On Wednesday, March 27, 2013, the Supreme Court heard oral argument on the issue of pharmaceutical patent settlement agreements between branded and generic drug companies that contain so-called “pay-for-delay” or “reverse payment” provisions. Federal Trade Commission v. Actavis, Inc., involves the Federal Trade Commission’s (FTC’s) appeal of the U.S. Court of Appeals for the 11th Circuit’s order affirming dismissal of an FTC charge that such an agreement was an unfair method of competition in violation of Section 5 of the Federal Trade Commission Act. Proof that an agreement between competitors is anticompetitive under Section 5 (which only the FTC may enforce) and under Section 1 of the Sherman Act (for which there is a private right of action) is essentially the same. The Supreme Court’s ruling in FTC v. Actavis will almost certainly have major implications for the viability of FTC and private suits alleging that pay-for-delay settlements are anticompetitive, and for the level of antitrust risk facing companies that enter into such settlements.
before patent expiration and did not otherwise allegedly fail the foregoing tests, the 11th Circuit affirmed
dismissal of the FTC complaint. The Supreme Court likely accepted the case because of a circuit split on this
issue. In 2012, in In re K-Dur Antitrust Litigation, in which the FTC was not a party, the Third Circuit reversed a
district court and applied a legal analysis that rejects the scope-of-the-patent test and essentially adopts the
FTC approach.

In the oral argument, the Justices directed a number of pointed questions and comments to each side. As noted,
the government would put the burden on defendants to show that their agreement is not anticompetitive, arguing
that “agreements of this sort should be treated as presumptively unlawful, with the presumption able to be
rebutted in various ways” that do not include an assessment of the patent’s validity or of the strength of the
infringement claim. Members of the Supreme Court expressed skepticism about that rule. Justice Kennedy
responded, “[t]hat’s my concern, is your test is the same for a very weak patent as a very strong patent. That
doesn’t make a lot of sense.” Justice Scalia said that to not evaluate the strength of the patent in assessing
competitive effects is to leave out “the elephant in the room.” Justice Breyer remarked that the government
proposes “a whole set of complex per se burden of proof rules that I have never seen in other antitrust cases,”
adding, “I’m worried about creating some kind of administrative monster.”

Justices also had pointed comments for the companies’ counsel, particularly on whether it is appropriate to find
that the patent has an absolute right to exclude even though it was being tested in court. The companies’
counsel argued that “the patent gives the patentholder the legal right to exclude” and that unless the patent is
legally unenforceable, the patentholder is “entitled to monopoly profits for the whole duration of the patent.”
Justice Sotomayor said “there is no presumption of infringement” by the generic product, “[s]o what you’re
arguing is that in fact a settlement of an infringement action is now creating the presumption.” She added, “I
don’t know why we would be required to accept that there has or would be infringement by the product that has
voluntarily decided not to pursue its rights.” Justice Kagan remarked that “[i]t’s clear what’s going on here is
that [the brand and generic firms are] splitting monopoly profits and the person who’s going to be injured are all
the consumers out there,” and that under the companies’ proposed rule, the brand and generic firm will have the
incentive “in every single case . . . to split monopoly profits in this way to the detriment of all consumers.”

The Supreme Court’s term concludes in June 2013, by which time a decision is expected.

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