Litigation Alert:

Supreme Court Rules on "Reverse Payment" Settlements in *Federal Trade Commission v. Actavis, Inc.*

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Today, the U.S. Supreme Court held in *Federal Trade Commission v. Actavis, Inc.* that so-called "reverse payment" settlement agreements should be analyzed under a rule-of-reason analysis under which the court assesses any anti-competitive effects of such agreements "by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances." 570 U.S. ___ (2013), Slip Op. at 9-10, 21. Reverse payment settlement agreements are a type of litigation settlement that requires the patent holder to pay the alleged infringer, often in exchange for the alleged infringer agreeing not to enter the market until a specified date. *See* 570 U.S. ___ (2013), Slip Op. at 1; *FTC v. Watson Pharms., Inc*., 677 F.3d 1298, 1301 (11th Cir. 2012).

In so holding, the Court rejected the rule previously adopted by the U.S. Courts of Appeals for the Eleventh, Second and Federal Circuits, under which a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent and there is no sham litigation or fraud in obtaining the patent. *Watson Pharms.*, 677 F.3d at 1312; *In re Tamoxifen Citrate Antitrust Litig*., 429 F.3d 370 (2d Cir. 2005), amended, 466 F.3d 187 (2d Cir. 2006), cert. denied, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litig*., 544 F.3d 1323 (Fed. Cir. 2008), cert. denied, 557 U.S. 920 (2009). The Court also rejected the rule previously used by the U.S. Court of Appeals for the Third Circuit, which treats reverse payment agreements as presumptively anticompetitive and unlawful unless the parties to the agreement can show that the payment was for a purpose other than delayed entry or it offered some pro-competitive benefit. *In re K-Dur Antitrust Litig*., 686 F.3d 197 (3d 2012), petitions for cert. pending, No. 12-245 (filed Aug. 24, 2012) and No. 12-265 (filed Aug. 29, 2012).

In *Actavis*, the Food and Drug Administration ("FDA") approved Solvay's New Drug Application ("NDA") for AndroGel, a topical gel that treats the symptoms of low testosterone in men, in February 2000.[1] *Watson Pharms.*, 677 F.3d at 1304. U.S. Patent No. 6,503,894 ("the '894 patent") issued on January 7, 2003. *Id*. The '894 patent did not expire until August 2020.[2] *Id*.

Two generic manufacturers — Watson Pharmaceuticals, Inc. and Paddock Laboratories, Inc. — filed Abbreviated New Drug Applications ("ANDA's") with the FDA in May 2003. *Id*. Both generic manufacturers made paragraph IV certifications, asserting that their generic AndroGel product did not infringe the '894 patent and/or that the '894 patent was invalid. *Id*. Solvay filed a patent infringement lawsuit in federal district court, which triggered a 30-month stay of the FDA's approval of Watson and Paddock's ANDA's. *Id*. Paddock partnered with Par Pharmaceutical Companies, Inc., which agreed to share Paddock's litigation costs in exchange for part of the potential profits from Paddock's generic AndroGel product if that product received final FDA approval. *Id*.

When the 30-month stay expired in January 2006, the parties had conducted discovery and the defendants' summary judgment motions on the issue of patent validity had been fully briefed, but not yet decided by the court. *Id*. at 1304-1305. The FDA approved Watson's generic AndroGel ANDA in January 2006 after expiration of the stay. *Id*. at 1304. However, in September 2006, before the district court ruled on the pending summary judgment motions and before any generic AndroGel was brought to market, the parties settled the patent litigation with a series of settlement agreements. *Id*. at 1305. Under the settlement agreements, Watson and Paddock/Par were granted a license to launch their generic AndroGel products

1 *Additional details of the Actavis case and the process by which brand name pharmaceutical manufacturers and generic companies introduce drugs to market are discussed in: Melanie L. Mayer and David K. Tellekson,* IP Litigation Alert: U.S. Supreme Court to Weigh In on Reverse Payment Deals, *April 2013, which is available at http://www.fenwick.com/publications/Pages/Litigation-Alert-US-Supreme-Court-to-Weigh-In-on-Reverse-Payment-Deals.aspx*

2 *The '894 patent was directed to the AndroGel formulation. A prior patent covering the synthetic testosterone in AndroGel had already expired.*

starting in August 2015 — five years before the '894 patent was set to expire. *Id*. Watson agreed to promote branded AndroGel to urologists, and Par agreed to promote it to primary care physicians. Par/Paddock also agreed to provide back-up manufacturing capabilities for the branded AndroGel product. *Id*. In return, Solvay agreed to pay Paddock/Par $10 million per year for six years and an additional $2 million per year for the back-up manufacturing services. *Id*. Solvay also agreed to share a portion of its AndroGel profits with Watson and projected that the payments to Watson would be between $19 million and $30 million per year. *Id*.

The settlement agreements were reported to the Federal Trade Commission ("FTC") as required by law, and the FTC subsequently filed an antitrust lawsuit against Solvay, Watson, Paddock and Par. *Id*. The FTC claimed that the settlement agreements were unlawful agreements not to compete in violation of Section 5(a) of the Federal Trade Commission Act. *Id*. According to the FTC, the agreements were attempts to defer generic competition for the branded AndroGel product by postponing the entry date of the generic drugs, which maintained Solvay's monopoly and allowed the parties to share those monopoly profits at the expense of consumers. *Id*. The FTC's claim was based on the FTC's allegation that Solvay would have lost the underlying patent litigation and the '894 patent would therefore not have barred the generic manufacturers from bringing their generic AndroGel products to market. *Id*.

The district court granted the defendants' Rule 12(b)(6) motion to dismiss the FTC's complaint because Eleventh Circuit precedent immunized reverse payment settlement agreements from antitrust attack unless a settlement imposes an exclusion greater than that contained in the patent at issue. *In re AndroGel Antitrust Litig*., 687 F.Supp.2d 1371 (N.D. Ga. 2010). The FTC had not alleged that the settlement agreements exceeded the scope of the '894 patent. Indeed, the settlement agreements provided that the generic manufacturers could market generic AndroGel five years *before* the '894 patent was set to expire. On appeal, the Eleventh Circuit affirmed the dismissal because the FTC had not alleged that the patent infringement litigation was a sham litigation, that the '894 patent was obtained by fraud, or that any anticompetitive effects of the settlement agreements were outside the scope of the exclusionary potential of the '894 patent. *Watson Pharms.*, 677 F.3d 1298 (11th Cir. 2012).

As discussed above, today the U.S. Supreme Court reversed the Eleventh Circuit, concluding that the Eleventh Circuit should have allowed the FTC's lawsuit to proceed using a rule-of-reason analysis. Aside from noting "traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances," 570 U.S. ___ (2013), Slip Op. at 9-10, Justice Breyer, writing for the majority[3], provided almost no guidance for how lower courts should analyze reverse payment agreements. Instead, the Court simply stated that "trial courts can structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other hand, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question – that of the presence of significant unjustified anticompetitive consequences." *Id.* at 21. Apparently struck by this lack of guidance, Chief Justice Roberts, writing for the dissent[4], commented, "Good luck to the district courts that must, when faced with a patent settlement, weigh the 'likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances.'" 570 U.S. ___ (2013), Dissenting Op. at 15.

Citing the Court's holdings in *United States v. Singer Mfg. Co*., 374 U.S. 174 (1963) and *United States v. New Wrinkle, Inc*., 342 U.S. 371 (1952), the Court asserts that its precedents make clear that patent-related settlement agreements can sometimes violate antitrust laws and that there is nothing novel about its holding in *FTC v. Actavis, Inc*. 570 U.S. ___ (2013), Slip Op. at 10, 12. However, Chief Justice Roberts disagreed, saying that *Singer* and *New Wrinkle* do not support the majority's rule, but instead stand for the proposition "that when a patent holder acts *outside* the scope of its patent, it is no longer protected from antitrust scrutiny by the patent." 570 U.S. ___ (2013), Dissenting Op. at 6 (emphasis in original). Chief Justice Roberts also commented:

3 The majority included Justice Breyer, Justice Kennedy, Justice Ginsburg, Justice Sotomayor, and Justice Kagan.

4 Justice Thomas and Justice Scalia joined Chief Justice Robert's dissent.

> The majority points to *no* case where a patent settlement was subject to antitrust scrutiny merely because the validity of the patent was uncertain. Not one. It is remarkable, and surely worth something, that in the 123 years since the Sherman Act was passed, we have never let antitrust law cross that Rubicon.

Id. at 8 (emphasis in original).

The majority does acknowledge that the Eleventh Circuit's rule[5] found support in the general policy favoring the settlement of disputes. The majority also acknowledged the Eleventh Circuit's "practical concern . . . that antitrust scrutiny of a reverse payment agreement would require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement." 570 U.S. ___ (2013), Slip Op. at 14. However, the Court concluded that five sets of considerations led them to adopt the rule-of-reason analysis: (1) "the specific restraint at issue has the 'potential for genuine adverse effects on competition'"; (2) "the[] anticompetitive consequences will at least sometimes prove unjustified"; (3) "where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice"; (4) "an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed"; and (5) "the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit." *Id*. at 14-19.

As the dissent points out, it is not clear that the Court's five sets of considerations are always true. For example, the Court posits that "an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed" because it concludes that "it is normally not necessary to litigate patent validity to answer the antitrust question." 570 U.S. ___ (2013), Slip Op. at 18. According to the majority, this is so because "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." *Id*. In that case, "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." *Id*. at 19. This assumption is, of course, not always true. As the dissent points out, "[a] patent holder may be 95% sure about the validity of its patent, but particularly risk averse or litigation averse, and willing to pay a good deal of money to rid itself of the 5% chance of a finding of invalidity." 570 U.S. ___ (2013), Dissenting Op. at 13. The dissent also explained:

> [I]n any such antitrust suit, the defendant (patent holder) will want to use the validity of his patent as a defense – in other words, he'll want to say "I can do this because I have a valid patent that lets me do this." I therefore don't see how the majority can conclude that it won't normally be "necessary to litigate patent validity to answer the antitrust question," unless it means to suggest that the defendant (patent holder) cannot raise his patent as a defense in an antitrust suit. But depriving him of such a defense – if that's what the majority means to do – defeats the point of the patent, which is to confer a *lawful* monopoly on its holder.

570 U.S. ___ (2013), Dissenting Op. at 12 (emphasis in original; internal citations omitted).

It also remains unclear how far the Court's holding in *FTC v. Actavis, Inc.* will reach. While this opinion addresses reverse payment agreements in the context of Hatch-Waxman patent litigation, the Court's opinion could be read as applicable to any settlement agreement that involves intellectual property rights and includes a "large" payment to the alleged infringer. Although the majority asserts that "most if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation," 570 U.S. ___ (2013), Slip Op. at 2, Chief Justice Roberts describes this characterization as "unlikely" and "fear[s] the Court's attempt to limit its holding to the context of patent settlements under Hatch-Waxman will not long hold." 570 U.S. ___ (2013), Dissenting Op. at 11.

It remains to be seen if *FTC v. Actavis, Inc.* will affect either the number of reverse payment agreements or

5 As discussed above, the U.S. Court of Appeals for the Eleventh Circuit adopted a rule that, absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent. Watson Pharms., 677 F.3d at 1312.

the number of ANDA's filed by generic pharmaceutical manufacturers. The Court appears to acknowledge that its holding may reduce the number of settlements, but suggests that the parties to a Hatch-Waxman patent litigation may still "settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." 570 U.S. ___ (2013), Slip Op. at 14, 19. However, as the dissent points out, it may be that "there . . . [is] no incentive to settle if, immediately after settling, the parties would have to litigate the same issue – the question of patent validity – as part of a defense against an antitrust suit." 570 U.S. ___ (2013), Dissenting Op. at 11.

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