Litigation Alert:

U.S. Supreme Court to Weigh In on Reverse Payment Deals

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On March 25, 2013, the U.S. Supreme Court heard oral argument in *FTC v. Actavis, Inc.*,[1] which is on appeal from the U.S. Court of Appeals for the Eleventh Circuit. This case addresses a type of patent litigation settlement most common in the pharmaceutical industry sometimes referred to as a "reverse payment" or "pay for delay" agreement. As the Eleventh Circuit explained, in a reverse payment settlement, the patent holder pays the allegedly infringing generic drug company to delay entering the market until a specified date, which protects the patent monopoly against a judgment that the patent is invalid or would not be infringed by the generic company's product. *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1301 (11th Cir. 2012).

To put this case in context, it is helpful to have an understanding of the process by which brand name pharmaceutical manufacturers and generic companies introduce drugs to market. One way a brand name manufacturer initiates approval for a new drug is to submit a New Drug Application ("NDA") to the Food and Drug Administration ("FDA") with detailed information about the drug, including data that demonstrates the safety and efficacy of the drug. 21 U.S.C. § 355(b)(1). The NDA applicant must also provide the FDA with the patent numbers of any patent that a generic manufacturer would infringe by making or selling the NDA applicant's drug. 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(b). If the FDA approves the NDA, the drug and patent information is published in a book commonly known as the "Orange Book."

To obtain FDA approval of a generic drug, a generic manufacturer is allowed to follow a much less rigorous procedure outlined by the Hatch-Waxman Act. The generic applicant files an Abbreviated New Drug Application ("ANDA"), which allows that applicant to rely on the safety and efficacy studies supplied by the brand name manufacturer if the generic manufacturer shows that its generic product contains the same active ingredient as, and is bioequivalent to, the brand name drug. *See* 21 U.S.C. § 355(j).

If a generic applicant is filing an ANDA for a drug listed in the Orange Book, the ANDA applicant must make one of four certifications with respect to any patents associated with the drug. In particular, the ANDA applicant must certify that: (I) no patent information for the brand name drug has been filed; (II) the patent has expired; (III) the patent will expire on a specified date; or (IV) the "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii). If the ANDA applicant certifies under paragraph IV, then it must send notice to the patent holder. 21 U.S.C. § 355(j)(2)(B). The paragraph IV certification is deemed a constructive act of infringement, and the patent holder then has 45 days to file an infringement lawsuit against the ANDA applicant. 35 U.S.C. § 271(e)(2)(A); 21 U.S.C. § 355(c)(3)(C). If the patent holder does not bring suit, the FDA may approve the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). However, when a lawsuit is filed within 45 days, the FDA generally may not grant final approval of the ANDA for 30 months after the lawsuit is filed or until the ANDA filer prevails in litigation, whichever occurs first. 21 U.S.C. § 355(j)(5)(B)(iii). If patent validity and infringement remain unresolved after the 30 month stay, the FDA may proceed to approve the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A). In this situation, the generic may launch the generic drug, but risks being liable for damages if the patent is ultimately held to be valid and infringed.

The Hatch-Waxman Act provides an incentive for generic drug manufacturers to file ANDA applications making a paragraph IV certification. More specifically, the first ANDA applicant making a paragraph IV certification that receives FDA approval is granted a 180-day period of exclusivity during which the FDA postpones the approval of any other ANDA applications for a generic version of the same Orange Book listed drug.[2] 21 U.S.C. § 355(j)(5)(B)(iv).

In the *Actavis* case, Besins Healthcare, S.A., developed AndroGel, a topical gel that treats the

1 Defendant Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc.

2 The 2003 amendments to the Hatch-Waxman Act enacted as part of the Medicare Modernization Act ("MMA") added forfeiture provisions that can deprive the first-filer of exclusivity. The settlements at issue in *FTC v. Actavis, Inc.* involve ANDA's governed by pre-MMA law.

symptoms of low testosterone in men. Besins granted Solvay Pharmaceuticals, Inc. a license to sell AndroGel in the United States and agreed to provide a commercial supply of the drug if the FDA approved it. Solvay filed an NDA for AndroGel in April 1999, and the FDA approved the NDA in February 2000. After the United States Patent and Trademark Office awarded Solvay and Besins with U.S. Patent No. 6,503,894 ("the '894 patent") on January 7, 2003, Solvay asked the FDA to include the '894 patent in the Orange Book for the AndroGel listing. The '894 patent did not expire until August 2020.[3]

Two generic manufacturers , Watson Pharmaceuticals, Inc. and Paddock Laboratories, Inc., filed ANDA's with the FDA in May 2003. As the first party to file an ANDA, Watson was eligible for a 180-day period of exclusivity. Both generic manufacturers made paragraph IV certifications, asserting that their generic AndroGel did not infringe the '894 patent and/or that the '894 patent was invalid. Solvay filed a patent infringement lawsuit in federal district court within the 45-day window, triggering the 30-month stay of the FDA's approval of Watson and Paddock's ANDA's. 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.

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. The FDA approved Watson's generic AndroGel ANDA in January 2006 after expiration of the stay.

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. Under the settlement agreements, Watson and Paddock/Par were granted a license to launch their generic AndroGel products starting in August 2015 — five years before the '894 patent was set to expire. 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. 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. 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.

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. 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. 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. 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.

The district court granted the defendants' Rule 12(b)(6) motion to dismiss the FTC's complaint. *In re AndroGel Antitrust Litig*., 687 F.Supp.2d 1371 (N.D. Ga. 2010). The district court agreed with the defendants that 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. 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. Therefore, the district court held that the FTC had failed to state a claim on which relief could be granted.

The FTC appealed to the Eleventh Circuit Court of Appeals. The FTC urged the Eleventh Circuit to adopt "a rule that an exclusion payment is unlawful if, viewing the situation objectively as of the time of the settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date." *Watson Pharms*., 677 F.3d at 1312. The FTC argued that its complaint stated a plausible anti-trust claim under that rule because the complaint alleged that Solvay was "not likely to prevail" in the underlying infringement action so the '894 patent was unlikely to prevent generic entry. *Id*.

3 The '894 patent was directed to the AndroGel formulation. *Watson Pharms*., 677 F.3d at 1304. A prior patent covering the synthetic testosterone in AndroGel had already expired. *Id*.

The Eleventh Circuit rejected the FTC's proposed rule for several reasons. First, the court found that the FTC's rule "equates a likely result (failure of an infringement claim) with an actual result, but it is simply not true that an infringement claim that is 'likely' to fail actually will fail." *Id*. at 1312. Second, the FTC's rule would require a difficult and unreliable "after-the-fact calculation of how 'likely' a patent holder was to succeed in a settled lawsuit if it had not been settled." *Id*. at 1313. Moreover, the FTC's rule, which requires the court hearing the antitrust claim to adjudicate the merits of the underlying patent infringement claim, would be in tension with Congress' decision to have appeals involving patent issues decided by the United States Court of Appeals for the Federal Circuit. *Id*. at 1315.

The Eleventh Circuit concluded that its precedents established 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." *Id*. at 1312. The Eleventh Circuit explained that the exclusionary potential of the patent derives from the "exclusionary rights appearing on the patent's face and not the underlying merits of the infringement claim." *Id*. at 1311, n.8. 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, the Eleventh Circuit affirmed the district court's dismissal of the FTC's antitrust claim. The FTC's petition for rehearing en banc was denied.

At the FTC's request, the Solicitor General of the United States petitioned the U.S. Supreme Court to review the Eleventh Circuit's ruling. As explained in the petition for *certiorari*, the U.S. Courts of Appeal have treated reverse payment settlement agreements differently. The Eleventh, Second and Federal Circuits have held that federal competition law permits reverse payment agreements unless the underlying patent litigation was a sham, the patent was obtained by fraud, or the agreement's anticompetitive effect is outside the scope of the exclusionary potential of the patent. *Watson Pharms*., 677 F.3d 1298; *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). In contrast, the Third Circuit views such agreements as closely resembling practices condemned as *per se* anticompetitive and treats them 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). The U.S. Supreme Court granted *certiorari*.

When the FTC presented its arguments to the court of appeals, it appreciated that Eleventh Circuit precedent instructed that reverse settlement agreements should be assessed by determining whether the settlement fell "within the scope of the exclusionary potential of the patent." Therefore, the FTC urged the Eleventh Circuit to find that, when assessing "the exclusionary potential of the patent," a court should consider whether it was "more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date." *Watson Pharms*., 677 F.3d at 1312. However, the FTC abandoned this position in its briefing to the U.S. Supreme Court, characterizing it as "doctrinally anomalous and likely unworkable in practice." Brief for FTC ("FTC Br.") at 53.

Instead, in its briefing to the U.S. Supreme Court, the FTC advocated for an approach similar to that taken by the Third Circuit in which reverse payment agreements are presumptively anticompetitive under a burden-shifting "quick look" analysis. FTC Br. at 17. Under the FTC's proposed rule, a reverse payment settlement that includes a "payment" and a deferred generic entry date would be presumed unlawful and the settling parties would have the burden of rebutting that presumption. *Id*. The settling parties could attempt to rebut the presumption by presenting evidence that the payments were consideration for unrelated property or services, that the payment was commensurate with the litigation costs that the brand-name manufacturer would otherwise have borne, or in rare circumstances, by presenting "other unusual business or litigation justifications." *Id*.

The FTC argued that a "quick look" analysis was appropriate to analyze reverse payment agreements because such agreements resemble other horizontal agreements between competitors that are *per se* unlawful under federal competition law. *Id*. at 20-24.

The FTC described the reverse payment situation in the pharmaceutical industry as follows:

> a brand-name manufacturer's monopoly profits will greatly exceed the combined profits that the brand-name and generic manufacturers could earn if they competed against each other for sales of the same drug. The brand-name manufacturer's monopoly profits are large enough to pay its would-be generic competitors more than they could hope to earn if they entered the market, while still leaving the brand-name manufacturer greater profits than it could earn in the face of generic competition.

Id. at 21. According to the FTC, "the two manufacturers are not simply deciding how a fixed pool of profits will be divided between them…, but are also controlling how large the combined pool will be." *Id*. at 22.

Echoing the Third Circuit's opinion in *In re K-Dur Antitrust Litig*., the FTC argued that the scope-of-the-patent approach used by the Eleventh, Second and Federal Circuits gives no meaningful antitrust scrutiny to reverse payment agreements. The FTC characterized the scope-of-the-patent rule as "allow[ing] the patentee to purchase the same period of exclusivity that a successful infringement suit would produce, even if all would concede that the patentee had little likelihood of prevailing in the infringement litigation." *Id*. at 44. The FTC also warned that adoption of the scope-of-the-patent approach would result in consumers bearing the costs of an increased frequency and severity of reverse-payment agreements. *Id*. at 45.

The FTC acknowledged that analyzing reverse payment settlements under a "quick look" approach would result in fewer settlements, but argued that their rule was nonetheless more in keeping with the policies of the Hatch-Waxman Act. *Id*. at 46-49. According to the FTC, parties wishing to settle a Hatch-Waxman lawsuit would still have "broad latitude" to enter settlement agreements that did not include a reverse payment. *Id*. at 46. The FTC also argued that Hatch-Waxman settlements are not always in the public interest as the public would benefit from judicial testing of patent scope and the elimination of invalid patents. *Id*. at 48.

In response, Actavis, Solvay and Par/Paddock argued that there was no legal support for assessing reverse payment agreements under a "quick look" analysis. U.S. Supreme Court precedent instructed that a "quick look" approach is only used to assess arrangements that resemble practices that are *per se* illegal and for which the anticompetitive effects can easily be ascertained. *See* Brief of Actavis ("Actavis Br.") at 21-23; Brief of Solvay ("Solvay Br.") at 24-25; Brief of Par/Paddock ("Par Br.") at 5-6. However, reverse payment settlements do not resemble any practice that is *per se* illegal, and the FTC had failed to demonstrate *any* actual or theoretical anticompetitive effects. *See* Actavis Br. at 23-29; Solvay Br. at 30-34. Respondents pointed out that leading economists — and until recently even the Department of Justice — agree that the presence of a "payment" without more was an insufficient indicator of the competitive effects of a patent litigation settlement. *See* Actavis Br. at 24-27.

Respondents criticized the FTC's proposed rule for completely ignoring the patent, which grants the holder the *lawful* right to exclude competition within its scope. *See* Actavis Br. at 18-20; Solvay Br. at 14-16; Par Br. at 31-58. Respondents pointed out that Supreme Court precedent teaches that good-faith claims of patent validity and infringement must be assumed true for antitrust purposes unless the patent is adjudicated invalid or not infringed. *See* Actavis Br. at 18-20; Solvay Br. at 16-19. In contrast, the FTC's proposed rule is premised on "the radical proposition that a patent is entitled to no weight at all unless and until it is proven valid and infringed in litigation." Actavis Br. at 3.

Respondents also criticized the FTC's proposed rule as setting an "alarmingly low" bar for pleading an antitrust violation. Actavis Br. at 36. The antitrust plaintiff would only have to allege a "payment" and a non-immediate generic entry, but there was no requirement that the plaintiff show that the "payment" actually resulted in any delay. Actavis Br. at 35-36. In addition, the "payment" could include not only monetary consideration, but also any economic value *in any form*, which Actavis characterized as "hopelessly ambiguous." Actavis Br. at 13, 32-35. A deferred entry date could presumably be plead by simply alleging a non-immediate generic entry date without any showing that the agreed upon date was delayed beyond what the parties would have agreed to absent any payment. *See* Actavis Br. at 35. Moreover, the FTC's rule appears to preclude the settling parties from attempting to prove that there was no actual delayed generic entry because this could likely only be ascertained by re-litigating the patent merits — a task the FTC agreed was likely unworkable in practice. *See* Actavis Br. at 36-39. Therefore, the FTC's proposed rule is in effect a *per se* prohibition of any reverse settlement agreements, including those with pro-competitive effects. *See* Actavis Br. at 36-39; Solvay Br. at 22-23.

Respondents further argued that the FTC's proposed rule would not achieve its policy objectives. For example, according to respondents, the FTC's rule would have a chilling effect on generic patent challenges and on pharmaceutical innovation because there would be no meaningful settlement option. *See* Actavis Br. at 39-40; Solvay Br. at 35-36. The parties would be forced to litigate their patent disputes to conclusion because, if they settled, they would be exposed to lawsuits from treble-damage-seeking antitrust plaintiffs who would benefit from an easy-to-establish *prima facie* case and a presumption that the settlement was illegal. *See* Actavis Br. at 17; Solvay Br. at 57-59. The Respondents urged that, to the extent that the Hatch-Waxman Act has created any undesirable policies, Congress — and not the courts — should formulate new rules. *See* Actavis Br. at 57; Solvay Br. at 51.

The Respondents urged the U.S. Supreme Court to adopt the scope-of-the-patent rule used by the Eleventh, Second and Federal Circuits to analyze reverse payment settlements. *See* Actavis Br. at 46-57; Solvay Br. at 19-21. This rule is consistent with Supreme Court precedent and properly considers the existence of the patent in the antitrust analysis. *See* Actavis Br. at 46-52; Solvay Br. at 13-21. This rule also provides a clear metric for determining the legality of settlement agreements and is consistent with public policy favoring settlements. *See* Actavis Br. at 50-52.

At oral argument, the U.S. Supreme Court appeared conflicted about how to treat reverse payment agreements. Many members of the Court questioned why reverse payment agreements should not be assessed using the rule-of-reason test, under which courts would weigh both the pro- and anti-competitive effects of reverse payment agreements. For example, Justice Sotomayor asked Deputy Solicitor Malcolm Stewart, who appeared on behalf of the FTC, "why is the rule of reason so bad?" Justice Scalia questioned why the Court should "overturn understood antitrust laws…just to patch up a mistake that Hatch-Waxman made." And Justice Breyer was concerned about creating an "administrative monster," but suggested that the district court judge should be able to structure the case, with advice from the attorneys, to best assess any anticompetitive effects and business justifications.

Justice Sotomayor was also uneasy with the FTC's proposal to essentially put the burden of proof on the settling parties. Justice Sotomayor commented that she had "difficulty understanding why the mere existence of a reverse payment…changes the burden" and stated that it was plaintiffs that should "bear the burden…of proving that the payment for services or the value given was too high." The Deputy Solicitor responded that, if the Court "wanted to say that the plaintiff would bear the burden…that would be a fairly minor tweak to [the FTC's] theory."

Several members of the Court also expressed concern that reverse payment agreements could be a vehicle that the brand-name and generic drug manufacturers could use to share an increased pool of profits. Justice Sotomayor stated that a "reverse payment suggests…that they're sharing profits….I don't know what else you can conclude." Likewise, Justice Kagan questioned whether adopting the scope-of-the patent rule would incentivize the brand-name and generic manufacturers "to split monopoly profits…to the detriment of all consumers."

The U.S. Supreme Court's decision in *FTC v. Actavis, Inc*. is expected in early summer 2013.

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