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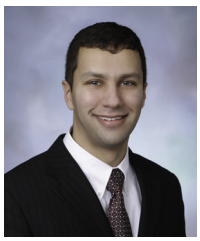
Reverse Payments After FTC v. Actavis: Supreme Court Unsettles Hatch-Waxman Patent Settlements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Patent litigation involving pharmaceutical products has been an especially robust area of law for at least the past 15 years, with literally billions of dollars riding on the outcome of individual cases. The stakes are high not only for the parties involved but also for patients and for the American health care system more broadly, because victory by a generic drug manufacturer can open the market for competition years ahead of a brand drug's patent expiration, reducing prices by 90% or more. The legal and regulatory scheme applicable to pharmaceuticals and pharmaceutical patent litigation is unique and complex, with asymmetric risks and rewards due to multiple factors, including: the widely divergent R&D cost structures and profit margins for branded and generic drugs; the fungibility of generic and branded versions of a drug under federal and state laws; and market distortions for pharmaceuticals created by private and governmental health care programs.

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Faced with all this, plus the fact that the outcome of any patent litigation is inherently highly uncertain, it is no surprise that as repeat litigants under this scheme, the innovator and generic drug industries have over the years crafted negotiated settlement structures for these types of cases. Almost universally, these settlements: allow early generic entry before a patent expires; recognize the legally presumptive validity of the issued patent; reduce legal and business uncertainty; eliminate litigation costs; conserve judicial resources; and allow companies to redirect their resources and energy to develop their next breakthrough drug or cost-saving generic product for the public benefit.

An additional key feature of these settlements, however—the payment of money from the patentee to the generic challenger (a so-called reverse payment)—has long been viewed by the Federal Trade Commission as anti-competitive in violation of the antitrust laws. The FTC thus won a significant victory when, on June 17, 2013, the Supreme Court overturned the then-prevailing doctrine that treated such settlements as immune from antitrust scrutiny so long as the patentee did not obtain rights beyond those available to it within the ''scope of the patent'' (11 PLIR 771, 6/21/13). The Court did not declare such settlements *per se* unlawful, nor did it adopt a rebuttable presumption of illegality (as FTC had urged). Rather, with its ruling the Court has now unshackled the FTC as well as private plaintiffs to pursue antitrust cases against brand and generic drug companies under the amorphous ''rule of reason.'' To complicate matters, however, the Court's decision raised multiple new questions while providing little in

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the way of concrete rules for the lower courts to use in what will likely be a blizzard of new antitrust cases.

This article summarizes the regulatory and legal background that fostered the development of reverse payment settlements, describes the FTC's decade-long crusade against such settlements and the lower courts' responses thereto, sets forth the basics of the settlement agreement at issue here, analyzes Justice Breyer's majority opinion and Chief Justice Roberts' dissent, and explores some of the potential legal, business, and public policy implications of this case.

Background – The Hatch-Waxman Amendments

Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the ''Hatch-Waxman Amendments''), a generic drug company may obtain Food and Drug Administration approval of a generic drug product by filing an Abbreviated New Drug Application (''ANDA'') that takes advantage of previous clinical testing conducted by the manufacturer of the corresponding brand-name drug product. The ANDA filer need only demonstrate that its formulation is materially the same as the branded drug (in terms of active ingredient, dosage form, strength, and route of administration) and that it is bioequivalent to the approved branded formulation. This abbreviated regulatory approval pathway would not by itself, however, guarantee prompt generic market entry due to the overhanging risk of crippling patent infringement damages if a generic were launched prior to patent expiration. Thus, Hatch-Waxman also established a system whereby generic applicants could seek judicial resolution of any patent infringement issues without first launching their product.

To obtain the patent certainty needed to facilitate a generic launch, the ANDA applicant may include a so-called Paragraph IV Certification in its ANDA, notifying FDA that the applicant believes its product would not infringe specified patents on the branded drug. Filing such a Paragraph IV Certification is defined as an act of patent infringement,[1] which gives the federal courts jurisdiction to decide whether the patent is invalid and/or whether the generic drug would infringe the patent, before any generic sales have been made. Generic applicants are not subject to monetary damages if they are found to infringe, unless they have made commercial sales of their product. Recognizing the critical importance of patent rights, especially in the field of medical research, Hatch-Waxman bars FDA approval of the Paragraph IV ANDA for a potentially infringing generic product for 30 months, to give the courts time to resolve the patent challenge. However, if the court has not decided the case by the 30-month date, FDA is free to approve the ANDA and the applicant may choose to begin marketing its generic drug ''at risk'' of later being found to infringe and subject to monetary (potentially treble) damages.

To incentivize generics to challenge a brand company's patents and pursue the ensuing litigation, Hatch-Waxman offers the first Paragraph IV ANDA filer the reward of 180 days of marketing exclusivity during which no other generic competitors are permitted to enter the market. The 180-day exclusivity period can be extremely lucrative, especially for generic versions of blockbuster drugs, and for small generic companies. But even being a subsequent, non-exclusive, generic entrant is a very attractive business proposition, as evidenced by the near ubiquitous Paragraph IV ANDAs filed by generic applicants after it is known that another company has established its First Filer status. If a Paragraph IV applicant loses its patent challenge it does not face damages (absent sales) but it will be forced to await the expiration of the full term of the patent(s). Given the high reward/low risk calculus of the Paragraph IV ANDA business model, virtually every new drug product faces the prospect of a patent challenge within the first five years or less of its marketing approval by FDA.[2]

The AndroGel Settlement

This case involved a Paragraph IV patent challenge over the topical testosterone replacement therapy AndroGel, marketed by Solvay Pharmaceuticals. Paddock Laboratories and Watson Pharmaceuticals (now Actavis) applied to market generic versions of the product in advance of the expiration date of Solvay's AndroGel patent. As is normal, Solvay sued to enforce its patent and several years of litigation ensued. In 2006, after the 30-month stay expired and the FDA proceeded with final approval of Watson's ANDA, the parties decided to settle the litigation.

The settlement contained several provisions. Watson and Paddock agreed not to market generic versions of AndroGel until August 31, 2015—five years prior to the expiration of Solvay's patent—so long as no other manufacturer began marketing a generic AndroGel product before then. Watson and Paddock also agreed to market AndroGel on behalf of Solvay to prescribers through September 2015. In return, Solvay agreed to pay Paddock $60 million over six years and agreed with Watson to share AndroGel profits valued at $19 million to $30 million per year. Importantly, each party benefitted by obtaining business certainty and the elimination of additional litigation costs, and the generic companies and American consumers benefitted from guaranteed generic entry five years earlier than would have been the case under the Solvay patent.

In 2009, the FTC sued Solvay and the generic companies, alleging that the reverse payment agreement constituted an unfair restraint of trade, was constructed to protect monopoly profits, and thereby violated federal antitrust laws. The district court dismissed the complaint for failure to state a claim.[3] The Eleventh Circuit affirmed the dismissal, finding no antitrust violation because under the settlement the generics were still scheduled to enter the market before Solvay's patent expired.[4]

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[1] 35 U.S.C. § 271(e)(2)(A).

[2] Indeed, under 21 U.S.C. § 355(c)(3)(E)(ii), no ANDA may be submitted to FDA for review until four years after the approval of a New Drug Application (NDA) for a drug with a novel active ingredient, Thus, for many novel branded drugs, a slew of generic patent challengers file Paragraph IV ANDAs on the same date that is exactly four years after the brand drug's approval.

[3] *In re AndroGel Antitrust Litig. (No. II)*, 687 F. Supp. 2d 1371 (N.D. Ga. 2010).

[4] *FTC v. Watson Pharms.*, 677 F.3d 1298 (11th Cir. 2012) (10 PLIR 549, 4/27/12).

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The FTC Crusade Against Reverse Payments Finally Generates a Circuit Split

FTC's AndroGel lawsuit was not its first attack against reverse payment settlements—nor even its first attack within the Eleventh Circuit, despite its past failures both in the Eleventh Circuit and elsewhere to convince courts of the illegality of such deals. Indeed, the standard previously applied by the Eleventh Circuit—the ''scope of the patent'' test—was adopted by the majority of circuits that had considered the legality of reverse payments. The Second and Federal Circuits agreed with the Eleventh Circuit that reverse payment agreements are lawful ''unless the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection.' ''[5] In other cases, the Sixth Circuit never expressly adopted a rule on reverse payments, but indicated that some reverse payments could violate antitrust laws although within the scope of the patent, noting, ''a monopoly that naturally arises from a patent'' was not meant ''to bolster the patent's effectiveness in inhibiting competition.''[6] The D.C. Circuit followed similar reasoning as the Sixth Circuit.

The lack of any real Circuit split hindered FTC's prior petitions for Supreme Court review of the reverse payment issue, and its attempt to bring the AndroGel case before the high Court may have failed as well, but for an interesting decision from the Third Circuit, applying a quick look rule of reason test to determine that ''any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market [is] *prima facie* evidence of an unreasonable restraint of trade.''[7] Under this rule, settling pharmaceutical companies bear the burden of overcoming the presumption that their settlement was anticompetitive ''by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.''[8] In its *certiorari* petition, the FTC urged the Supreme Court to apply a quick look test to reverse payments, and after years of FTC efforts, on December 7, 2012, the Supreme Court granted review of the AndroGel case.[9]

The Supreme Court Muddies the Water

In his opinion for the Court, Justice Breyer acknowledged that while patents convey the legal right to exclude competition, even if a reverse payment ''agreement's anticompetitive effects fall within the scope of the exclusionary potential of the patent,'' this would not immunize the agreement from antitrust scrutiny. However, the Court did not rule that reverse payment settlements are either *per se* or presumptively unlawful, but rather that they may be scrutinized under the Rule of Reason.[10] Justice Breyer's opinion will lead the FTC and private litigants to begin flooding the courts with antitrust claims against past, present, and (if any) future Hatch-Waxman patent settlements.

Unfortunately, Justice Breyer's opinion provides little concrete guidance by which to evaluate the many and varied forms of such settlements, leading Chief Justice Roberts to empathize in his dissent: ''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.' ''[11] Indeed, the degree of equivocation in Justice Breyer's opinion is striking:

> In sum, a reverse payment, where large and unjustified, ***can*** bring with it the risk of significant anticompetitive effects; one who makes such a payment ***may*** be unable to explain and to justify it; such a firm or individual ***may*** well possess market power derived from the patent; a court, by examining the size of the payment, ***may*** well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties ***may*** well find ways to settle patent disputes without the use of reverse payments.[12]

While perhaps believing that he was equitably splitting the difference between the FTC and industry positions, Justice Breyer's open invitation to broadly litigate antitrust claims for Hatch-Waxman settlements under yet-to-be developed review standards will likely do more harm to industry and consumers than would have a straightforward decision either banning reverse payments outright, or immunizing them from antitrust scrutiny. In either case, industry and the courts would have had certainty about past and future settlements, and Congress would have been presented with a clearer policy question for potential legislative action on the subject of reverse payments.

Practical Impacts on Industry

The most immediate impact on industry is that many existing patent settlements may now be opened up for judicial scrutiny, at the whim of the FTC and class action plaintiffs lawyers. The facts of those settlements cannot of course be changed, but the risk of liability, and possible arguments to avoid liability, can be assessed (very roughly at best) based on scattered hints within the Court's opinion.

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[5] *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 212-13 (2d Cir. 2006); *see also In re Ciprofloxacin Hydrochloride Litigation*, 544 F.3d 1323, 1336 (Fed. Cir. 2008).

[6] *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003).

[7] *See In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012) (10 PLIR 917, 7/20/12). What makes this case especially interesting is that the FTC had already failed to demonstrate an antitrust violation for the same settlement in an earlier case before the Eleventh Circuit, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1069-71 (11th Cir. 2005).

[8] *Id.* at 218.

[9] *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir. 2012), *cert. granted*, 133 U.S.L.W. 787 (U.S. Dec. 7, 2012) (No. 12–416) (10 PLIR 1559, 12/14/12).

[10] Justices Kennedy, Ginsburg, Sotomayor, and Kagan joined Justice Breyer's opinion, while Chief Justice Roberts, joined by Justices Scalia and Thomas, dissented. Justice Alito took no part in the case.

[11] Slip Op., Dissent at 15.

[12] Slip Op. at 19-20 (emphasis added).

As a result of the Supreme Court's ruling, many existing patent settlements may now be opened up for judicial scrutiny, at the whim of the FTC and class action plaintiffs lawyers.

For example, the opinion repeatedly latches on to the notion that ''large'' and ''unexplained'' or ''unjustified'' reverse payments are suspect, although nowhere is the concept of ''large'' expressly defined by the Court. The Court does hint, however, that unacceptably ''large'' payments may include those that are for ''a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market,''[13] Assuming a 10:1 price differential between a patented drug and a generic sold in a post-patent multisource market, the generic's potential ''gain in profits'' is nowhere near the patentee's potential loss in profits, so the Court's suggested threshold for what is an unjustifiably ''large'' reverse payment is based on flawed understanding of the pharmaceutical marketplace and if the threshold is applied literally by the district courts, few if any reverse payments are likely to survive scrutiny.

The majority offers hope that ''[w]here a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.''[14] While avoidance of direct litigation costs is a legitimate goal of any settlement, as with measuring ''large'' by reference to the generic's profits, defining ''large'' as any amount greater than actual litigation costs avoided will likely also not save any existing settlements from adverse judgment. The Court's discussion of justifying a reverse payment as consideration for ancillary services is encouraging on its face, but in reality the FTC has, and will continue to, cast aspersions on such payment for services defenses, and the courts will now have to adjudicate such claims on a case-by-case basis across a wide variety of specific agreements. It is difficult to imagine a coherent and consistent judicial doctrine arising any time soon from either the district courts or the courts of appeals on this issue.

The Court's opinion also suggests that ''large'' reverse payments may, and perhaps should, be deemed by the courts as a sign of the patentee's subjective belief about the patent's strength, such that the larger the payment, the stronger the proof that the payment was anticompetitive:

> An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. . . . In a word, 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.[15]

Again, the term ''large'' is undefined in this context, and the Court does not seem to even recognize that a reverse payment of $100 million is equal to only 10% of profits on a $1 billion per year drug, whereas a 10% payment on a $50 million per year drug is $5 million, and the same percentage payment on a $20 million drug is only $2 million. The first example is numerically ''larger'' than the other two examples, but are any (or all) of the payment amounts ''large'' for purposes of the Court's antitrust analysis? No one can tell because the Court never explains.

Despite the majority's assurances to the contrary, defending a reverse payment in an antitrust action likely will involve hypothetical evaluations of how the patent case would have been decided if it had not been settled. At a minimum, it will involve disputes over the parties' subjective evaluations of the strength of their patent positions. As Chief Justice Roberts cautions,

> [t]he task of trying to discern whether a patent holder is motivated by uncertainty about its patent, or other legitimate factors like risk aversion, will be made all the more difficult by the fact that much of the evidence about the party's motivation may be embedded in legal advice from its attorney, which would presumably be shielded from discovery.[16]

Thus, companies defending antitrust cases may have to choose between forgoing a potential defense, or waiving (to a potentially broad extent) their attorney-client privilege on matters that may have continued legal and business significance in other contexts.

So what can companies do to settle currently pending lawsuits? The majority's suggestion that settlements may safely be based on ''traditional settlement considerations''[17] seems to be of little practical utility in the complex and uniquely regulated world of prescription pharmaceuticals, where the cost and profit structures, and asymmetric regulatory and commercial incentives of branded and generic competitors, not to mention the highly specialized patent litigation scheme, are all unlike any ''traditional'' industry. Structuring reverse payments as payment for ancillary services, while mentioned with a hint of approval by the Court, is far too risky and uncertain an approach at this early stage where neither the FTC nor any lower courts have opined on the approach in the context of the Supreme Court's decision. That said, what drug companies will be willing to risk liability by entering any new reverse payment settlement unless and until more clarity emerges?

The one type of settlement that seems fairly safe under the Court's decision would be one in which the patent holder ''allow[s] 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.''[18] Of course, such a settlement is not actually a ''reverse payment'' settlement, and it remains to be seen whether this approach, or any other current or novel approaches, prove attractive and practical to litigants in current or upcoming cases.

[13] Slip Op. at 15.
[14] Slip Op. at 17.
[15] Slip Op. at 19.
[16] Slip Op. at 13.
[17] Slip Op. at 17.
[18] *Id*. at 19.

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Conclusion

The Actavis decision will be a major topic of discussion, concern, and future litigation for years to come. The questions it raises far outnumber those that it answered. Gaining clarity and some semblance of a path forward for Hatch-Waxman patent litigants will take time and will be dependent in large part on how the FTC reacts in terms of filing and prosecuting new cases, and how the district courts throughout the country interpret and apply the decision in light of specific settlement facts presented for review. It is fair (if flippant) to say that there is no *risk* that conflicting interpretations will arise in different district courts and Circuit Courts—there is a *certainty* of such conflicts, or, if you will, a certainty of continued uncertainty as to what the law actually is in this space.

Companies operating under existing reverse payment agreements must prepare for the strong possibility that they will be subject to either an FTC enforcement action, a private class action lawsuit, or in many cases both. Current and near-future Hatch-Waxman litigants will likely tread very lightly around settlement agreements that could implicate antitrust liability in this new environment. Whether, as many have suggested, the decision causes more cases to be litigated to judgment, reduces the number of generic patent challenges, and/or reduces the rate of innovative R&D, are critical questions whose answers will be sought and debated by industry and policy makers alike.

Finally, the hidden genius (if any exists) of Justice Breyer's opinion may be that its inscrutability will cause so much pain and uncertainty within industry, and lure FTC and the plaintiffs' bar so far over the edge of aggressiveness, that lawmakers may decide enough is enough, and reach a consensus on legislative changes to establish certainty and predictability for the industry to allow it to return its focus and resources to what serves the American public best—developing and distributing lifesaving innovative and generic drug products. Indeed, depending on how harshly the new law of reverse payments develops, the industry may ultimately be attracted to a legislative bargain that bans reverse payment settlements in exchange for retroactive immunity for prior potentially violative agreements.