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I. INTRODUCTION

A Hatch-Waxman settlement case finally reached the Supreme Court, and when it did the Court in *FTC v. Actavis* [2] rejected both (a) the settling parties' view that any settlement within the scope of the patent at issue and not the result of sham litigation was legal (the "scope of the patent" test); and (b) the FTC's view that any settlement which involved a transfer of any money or asset from the patent owner to the challenger was presumptively illegal (the "presumptive illegality" test). The Court held that such settlements were subject to inquiry, and that certain of them could constitute antitrust violations under the rule of reason standard.[3]

II. THE *ACTAVIS* CASE

In the underlying litigation, Solvay Pharmaceuticals, Inc. ("Solvay") had settled infringement suits with would-be generic producers with an agreement that let the generics enter on a date certain (before the expiration of the patent at issue), and with payments to the alleged infringer in exchange for the performance of certain marketing and promotional services for Solvay. The FTC alleged that these services had little value and that the payments were really made to compensate the generics for agreeing to delay their entry into the market.

The district court dismissed the FTC's complaint under the "scope of the patent" test, and the Eleventh Circuit affirmed, holding 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."[4]

The Supreme Court reversed. The majority opinion authored by Justice Breyer held that antitrust challenges to reverse payment settlement agreements should be analyzed under the rule of reason. The Court recognized that the "scope of the patent" test was grounded on a strong policy consideration favoring settlements, and that the rule of reason would likely reduce the litigating parties' incentive to settle patent infringement suits. But the Court agreed with the FTC that "there is reason for concern" that reverse payment settlements "have significant adverse effects on competition," and that the "scope of the patent" test therefore did not subject such agreements to a sufficient amount of antitrust scrutiny.

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[2] *FTC v. Actavis, Inc. et al.*, 526 U. S. 756 (2013).

[3] Actavis, *id.* at 20.

[4] *FTC v. Watson Pharma.*, 677 F.3d 1298, 1312 (11th Cir. 2012). After the Court granted review, the case was renamed FTC v. Actavis.

However, the Court rejected the FTC's argument that reverse payment agreements are presumptively unlawful.[5] Since the dissent also rejected the FTC's argument, one of the less publicized results of the case is that the "presumption of illegality," which the FTC has been pushing, was rejected by all the Justices participating in the case.

In making its determination, the Court specifically pointed to "five sets of considerations,"[6] which it summarized as follows:

> [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[7]

The majority opinion raises some fascinating questions.

A. What Kinds of Settlements Are Now Permissible?

The Court states that it is permissible to negotiate a date certain for generic entry prior to the patent's expiration. It also states that cash payments to a generic company may be justified under certain limited circumstances, such as to compensate for litigation costs. And it is legal to pay fair value for services or products from the potential infringer. This last point may seem obvious, but it is key to any analysis of settlements going forward.

B. When Kinds of Settlements Are Now at Risk?

The Court repeatedly emphasizes that "An unexplained large reverse payment itself" suggests that the patentee has doubts about the patent's strength and survival.[8] As the Dissent points out, this is vastly over simplified. Even someone very confident about its patent knows that litigation is a risk, and for someone risk averse the payment may be worthwhile to avoid the risk of an erroneous lower court finding against the patent, even if that finding was likely to be reversed on appeal.[9] This, in turn, raises three more issues:

1. What is a "large" payment? The Court indicates merely that the scale of reverse payments should be weighed against the brand's anticipated litigation costs, the value of any services provided by the generic, and other justifications raised by the defendants. But what other justifications are allowed? A payment of $1 million may seem large in the context of a product that sells $10 million per year. But in the context of a $1 billion product, it would not seem large at all.

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[5] Actavis Opinion, *supra* note 3, at 20.

[6] *Id*. at 14.

[7] *Id*. at 19 (emphasis supplied).

[8] *Id*. at 18.

[9] Actavis Dissent, *supra* note 3, at 13. *See also* Bernard & Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir. B. J. 617 (2005-06), at pp. 626-627. The importance of allowing settlement to protect against unjustified theft of the innovator's intellectual property as a result of an erroneous trial court decision seems to be ignored here.

2. Do we really care if the patentee has "doubts" about the strength or survival of the patent, or is this a shorthand way of saying that such a large and unexplained payment suggests that the patent actually is invalid or not infringed? Having doubts does not equate to having a weak patent—recall the *Cipro* litigation[10] where Bayer settled the first case with Barr, sent the patent in for reexamination along with the full trial record, had the patent reissued. and then faced and defeated challenges by Ranbaxy, Schein, Mylan, and Carlsbad. In each case Bayer produced the record of the Barr case, and in each case Bayer litigated to a successful conclusion.[11] That first settlement payment certainly did not reflect a weakness in the patent.

3. What explanations will serve to justify an otherwise "large" reverse payment? The Court states that the payment may be an estimate of saved litigation expenses, or "may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item."[12]

Both the majority and the dissent in *Actavis* focus on settlements involving cash payments from the patentee to the alleged infringer. But such cash payments have become less and less common (even when they were held to be perfectly legal). Scott Hemphill has done extensive research as to the facts of the reverse payment cases, and the results are instructive:[13] Since 2005, the clear trend in the cases has been away from cash payments entirely. The settlements are being based on side deals, the kinds of "other services" that the Court in *Actavis* says may justify the "payment".[14]

So, if cash deals are out of fashion, how do we evaluate whether or not there has been that "unexplained large reverse payment" that triggers scrutiny?

III. THE FTC TELLS US WHAT WE SHOULD THINK *ACTAVIS* HELD

The FTC has been active in propagating an interesting, but ultimately vastly overbroad, interpretation of the *Actavis* holding. A good example is the Agency's Amicus brief in the *Effexor XR* Antitrust Litigation. There, the FTC opposes a settlement that involved the innovator granting the generic an exclusive license under its patent. As an added clause, the license also stated that no authorized generics would be launched.[15] The FTC seized on that redundant

[10] In re: Ciprofloxacin Hydrochloride Litigation, Arkansas Carpenters Health and Welfare v. Bayer AG, 604 F. 3d 98 (2nd Circuit 2010); cert. denied, 131 S. Ct. 1606 (2011).

[11] Ranbaxy withdrew its certification and abandoned the litigation; in the Schein and Mylan cases, Bayer won on Summary Judgment and the Court of Appeals for the Federal Circuit affirmed; Carlsbad's challenge to the patent was rejected in a bench trial, and it did not appeal. I want to thank counsel for Bayer for providing me with this information.

[12] Actavis Opinion, *supr*a note 3, at 17.

[13] *See* S. Hemphill, *An Aggregate Approach to Antitrust: Using New data and Rulemaking to Preserve Drug Competition*, 109 COLUMBIA L. REV. 629 (2009). Even those of us who disagree with Scott's conclusions and prescriptions owe him a debt of thanks for his work in obtaining and laying out the underlying data.

[14] *Id.* at 649 (Table 2).

[15] The actual license agreement is public, and may be found at http:///.sec.gov/Archives/edgar/data/5187/0001193125-06-040159.htm. Since an exclusive license precludes the licensor from granting any additional licenses, there was no need to elaborate further and exclude authorized generics, any more than there was any need to identify other licenses that were barred. If the FTC position is that

clause, and characterized the entire deal as an agreement not to launch an authorized generic version of the product.[16] The FTC would find this potentially illegal under *Actavis* based on a two-part test: (1) it gave the generic something that it could not have won in the litigation; and (2) it represented a carving up of "monopoly" profits from the product.[17]

The merits of the *Effexor* case are beyond the scope of this article. But the FTC's proposed standard for finding a violation eviscerates *Actavis*, and is simply a reversion to the presumptive illegality test that the Court unanimously rejected. To see why this is so, we need to unpack the FTC's two criteria for condemning a settlement:

1. The first test is that the settlement gave the generic something that it could not get if it won the litigation. But the Court specifically said that it is legal to pay fair value for services or products from the potential infringer.[18] So if the innovator paid the generic fair value for distributing the product, the FTC would find that the payment satisfies its first test for a violation, since the generic couldn't have gotten that agreement through the litigation—even though the Supreme Court used it as an example of a legitimate settlement approach. Since an exclusive license is not something that you can "win" in a patent case, all exclusive licenses are *per se* suspect to the FTC now.
2. The settlement represented a sharing of "monopoly profits" under the patent. This sounds good, but overlooks the elementary fact that money is fungible. If the innovator pays the generic $1 million as reimbursement of litigation costs in a settlement allowing entry on a given date, the Supreme Court says that is all right. But the FTC could claim that the money was really a payment for delay—since, but for the payment, the generic might have insisted on an earlier entry date, and therefore it is a carving up of the monopoly profit.

On the FTC interpretation, every settlement that involves anything other than a pre-expiration date certain for generic entry is potentially illegal. And, indeed, any such settlement is presumptively illegal if it meets the FTC's two-part test. But that test condemns things that the Court in *Actavis* specifically allowed. The FTC is trying to construct an opinion that the Court never issued and have us adopt a standard that the Court unanimously rejected.

IV. NOW WHAT?

While it will take time to thrash out what *Actavis* actually means in terms of conduct going forward, there are a couple of starting points on which we can focus:

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you cannot grant an exclusive license as part of a settlement because that would exclude allowing an authorized generic, I would respectfully suggest that it is going well beyond what the Court, or Congress, ever intended.

[16] *See* generally FTC Brief as Amicus Curiae, *In re Effexor XR Antitrust Litig.*, Case No. 3:11-cv-05479 (D.N.J. Aug. 14, 2013), *available at* http://www.ftc.gov/os/2013/08/130816effexoramicusbrief.pdf. ("FTC Effexor Brief"). There is an irony here in that the FTC originally wanted to ban authorized generics entirely, and its allies in Congress introduced bills as recently as 2011 to that effect; *see* http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/02/legislation-to-ban-authorized-generics-during-180-day-exclusivity-period-makes-a-comeback-in-congres.html]

[17] *Id.* at 15.

[18] Actavis Opinion, *supra* note 3 at 17.

A. The Legitimacy of Fair Value Deals

When we evaluate a settlement involving services or products provided by the alleged infringer, the question cannot rationally be whether the generic could have "won" that deal had it won the litigation.

That FTC approach would eliminate all settlements involving services, since no defendant in a patent case is likely to seek, much less win, an order that it be allowed to provide certain services to the patentee in exchange for payments. It also would eviscerate the Court's opinion as to legitimacy of fair value deals.

In our context, the question has to be "Notwithstanding the litigation, does this deal represent a fair value transaction for both parties?" Businesses value products and services every day, and those values should be the starting point for looking at a settlement. But since the parties know that the FTC and a veritable swarm of plaintiff's lawyers will be picking the deal apart, having the imprimatur of experts may be a wise investment.

B. Consideration

Any settlement agreement involves some sort of consideration to the defendant—whether in the form of foregone damages, express monetary payment, or other benefit. Settlement is a compromise, not a total surrender. So does the defendant have to show that the value of the consideration does not include a premium to the generic to stay out of the market? That would be to resurrect the presumption of illegality, which the Court decisively—indeed unanimously—rejected.

No rational company provides services without making a profit. Since there is no presumption of illegality, the burden is on the challenger to show that there is a premium and that such premium is not simply a fair profit in the transaction.

C. Legitimate Business Profits

There is another issue that seems to have been overlooked in the initial analyses, but may be the key to future cases. A payment with no explanation invites argument that it was for some malign purpose; in this case, delayed generic entry. Conversely, a payment that can be fully explained as compensating the generic for real services (say, distributing product) almost has to be legal. The alternative would be to hold that once patent litigation is filed the two parties cannot do ordinary business together, which would be ludicrous.

But if the business deal between the patentee and the potential infringer is good enough, even if entirely defensible at fair value, the profit on the side deal could be enough to convince the generic to agree to a later entry date even though there is no "payment" for delay at all.

Yet if you condemn a legitimate side deal simply because it can generate legitimate business profits for the generic, there is no stopping point and all settlements that are anything other than partial surrender by the patentee are illegal. Not even the FTC argued that, being

content to argue that a reverse payment created a presumption of illegality, a position that, as we noted earlier, the Court unanimously rejected in *Actavis*.[19]

V. CONCLUSION

So where are we right now? About all that we can say for sure is that economists and accounting consultants will be very fully and gainfully employed, at least until the dust settles here.

[19] The Dissent would have upheld the scope of the patent test. The Majority ordered a full rule of reason inquiry. There were no votes for the presumption of illegality that the FTC sought. And if you can't rely on fair value of deal as complete defense, we are then thrown back on strength of the patent, which the Court did not want to get into and, one might say, implicitly rejected as unworkable.