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Food and Drug Law, Regulation and Education

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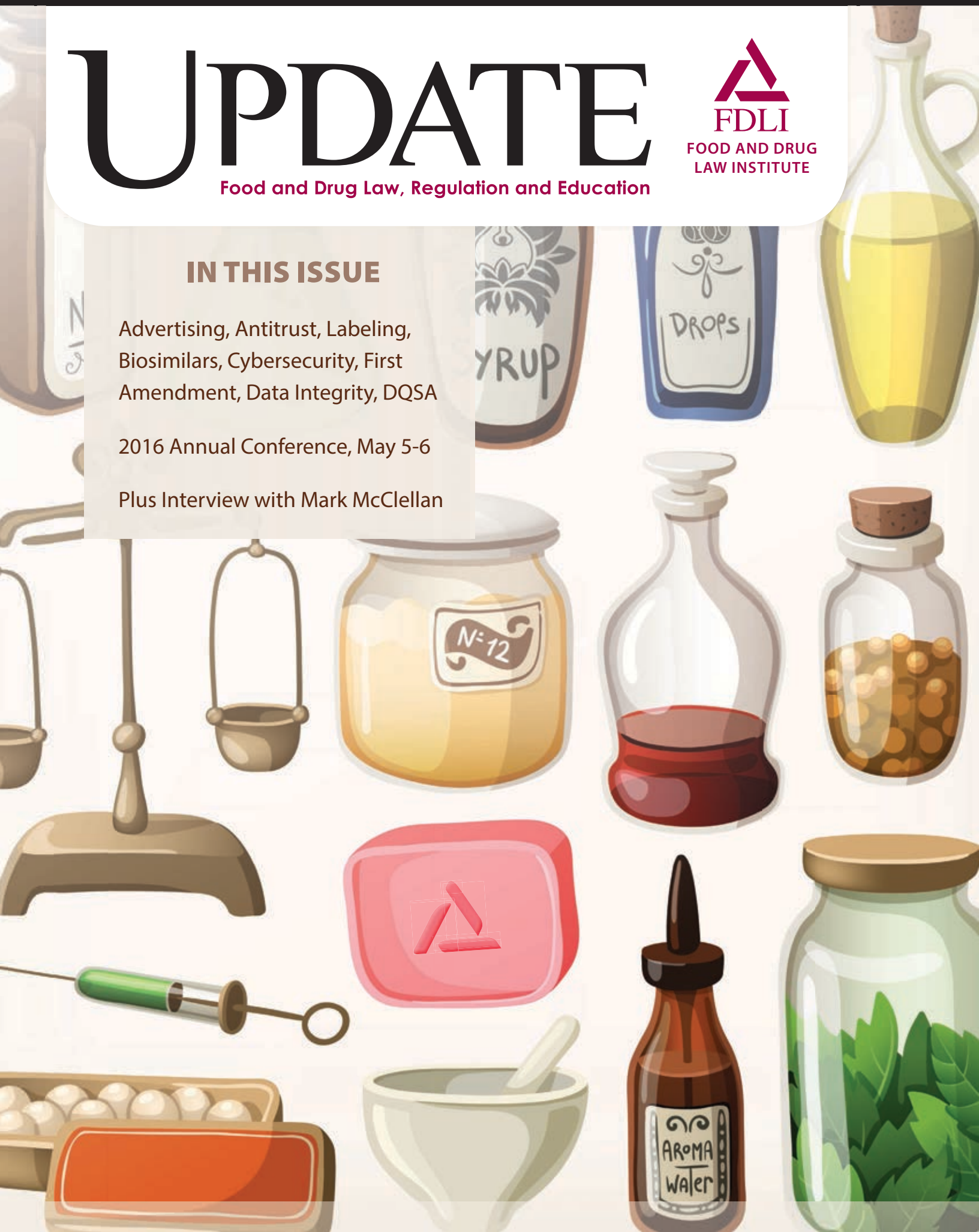

Antitrust Risks in Settling Hatch-Waxman Patent Litigation: Learning Since *Actavis*

By Megan Browdie and Howard Morse[1]

The U.S. Supreme Court waded into the murky waters of reverse-payment settlements of Hatch-Waxman patent litigation in its June 2013 decision, *Federal Trade Commission (FTC) v. Actavis*, concluding that such settlements "can sometimes violate the antitrust laws." The Court reasoned that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects," which outweigh the desirability of settlement, but refused to condemn all such settlements as "presumptively unlawful" as FTC urged.

Since that decision, lower courts have begun to apply *Actavis* and shed light on issues left open by the Supreme Court, including whether the ruling applies to non-cash payments, what constitutes a large and unjustified reverse payment, and how to structure antitrust litigation challenging a reverse payment. In the wake of *Actavis* and more recent court decisions, 2015 saw FTC's largest settlement ever: Teva Pharmaceutical Industries agreed to pay $1.2 billion to resolve claims it had paid to delay generic competition to its sleep disorder drug Provigil. The size of that settlement underscores the significant impact these legal issues can have on a pharmaceutical company's bottom line.

This article reviews recent lower court decisions and FTC enforcement actions to distill what practical guidance pharmaceutical companies looking to settle patent litigation can take from these developments.

The Reverse Payment Dilemma: How Did We Get Here?

A so-called "reverse payment" settlement may be entered to resolve Hatch-Waxman patent litigation when a prospective generic competitor seeks to enter before all patents have expired on a pioneer or "brand name" drug. Typically, the firms settle such litigation on terms that allow the generic to enter at some future date after the generic would enter were it to win the patent suit, but before the patent at issue would expire were the pioneer to win the lawsuit.

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FTC has challenged settlements that include a payment from the pioneer to the prospective generic, characterizing such payments as "reverse payments" because one normally expects an alleged infringer to pay the patent owner to settle patent litigation. FTC views such payments as "payments for delay," reasoning that the parties would have agreed to an earlier entry date in the absence of any payment.

Settling parties, on the other hand, have argued that any settlement allowing entry before all applicable patents expire is procompetitive since entry is within the scope of the exclusionary potential of the patent.

The Supreme Court addressed reverse payments in *FTC v. Actavis* to resolve a split in the circuit courts.[2] In that case, FTC sued a pioneer manufacturer and three firms that had filed Abbreviated New Drug Applications (ANDAs), arguing that the pioneer had paid the three to avoid facing generic competition for AndroGel, a testosterone replacement drug, in violation of the FTC Act's prohibition on "unfair methods of competition." The Eleventh Circuit affirmed the district court's dismissal of FTC's claim, holding that any anticompetitive effects fell within "the exclusionary potential of the patent," reasoning that patent owners have a "lawful right to exclude others," and that "public policy favor[s] settlement of disputes." The Third Circuit, by contrast, held in a similar case that a finder of fact must treat "any payment from a patent holder to a generic patent challenger who agrees to delay entry" as "prima facie evidence of an unreasonable restraint of trade," which could only be rebutted by showing the payment was for a purpose other than delayed entry or that it offered some procompetitive benefit.

The Supreme Court in *Actavis* held that reverse payment settlements can violate the antitrust laws when "large and unjustified" and that such settlements must be evaluated under the so-called antitrust "rule of reason." The Court held that the "likely anticompetitive effects" and "potential justifications" can be assessed by examining the size of a payment without litigating the validity of the patent, noting that "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." At the same time, the Court rejected FTC's position that any reverse payment should be "presumptively unlawful," reasoning that it would be inappropriate to shift to the defendant the burden of showing empirical evidence of procompetitive effects.[3]

While the contours of *Actavis* are still being fleshed out, early data suggests that there may have been a drop in the number of patent settlements with a reverse payment since the ruling. A recent FTC report advises that "[a]lthough the number of overall final settlements in FY 2014 was consistent with other recent years, the number of settlements potentially involving pay for delay decreased significantly in the wake of the *Actavis* decision." A close look, however, reveals that the data does not distinguish between payments that may be attributable to "avoided litigation costs" or "fair value of services," two categories of payments that the Supreme Court in *Actavis* concluded were "legitimate" and "lawful[]."[4]

What Aspects of an Agreement Increase or Decrease Risk?

The *Actavis* decision directs lower courts to consider a number of factors in evaluating potential reverse payment settlements: (1) whether the pioneer has market power that would enable it to work unjustified anticompetitive harm; (2) whether the size of the payment is so large that it suggests that the patentee had serious doubts about the patent's survival, which in turn suggests the payment's objective was to maintain supracompetitive prices; (3) whether the payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services; and (4) the parties' reasons for agreeing to the settlement terms.[5]

What to do with these factors has been the focus of post-*Actavis* litigation. While courts have varied in their analysis and outcomes, four key questions have bubbled to the surface: (1) whether the Supreme Court's ruling applies to non-cash payments; (2) how to determine if a payment is "large"; (3) how a court should determine whether a payment for services justifies a large payment; and (4) whether private plaintiffs must show but-for causation to recover damages.

Non-Cash Payments Are Probably "Payments" Under Actavis

One of the issues courts have grappled with in applying *Actavis* is whether a settlement must provide for a cash payment in order to be considered a "reverse payment."

Some courts initially concluded that *Actavis* applies only to cash payments, reasoning that "[b]oth the majority and dissenting opinions reek with discussion of payment of money." Because *Actavis* represented a significant shift in law, one district

court reasoned, "a cavalier extension … to any non-cash settlement package" would be contrary to the public policy of common law.[6]

Most courts, however, have come to the conclusion that *Actavis* applies with equal force to non-cash forms of consideration, including agreements by a pioneer manufacturer not to introduce an authorized generic during the 180 days that the Hatch-Waxman Act prohibits FDA from approving another ANDA (a no-AG agreement). As one court put it, "if antitrust scrutiny can be avoided simply by making one's large and unjustifiable reverse-payment settlement in gold bullion rather than dollars, then *Actavis* stands for nothing but an arbitrary restriction on the form such payments can take. To read the decision that way is to cabin its reasoning to the point of meaninglessness."[7]

In its 2015 decision in *King Drug Co. v. SmithKline Beecham Corp.*, the Third Circuit agreed that non-cash forms of compensation, including no-AG agreements, can be anticompetitive.[8] It concluded that "no-AG agreements are likely to present the same types of problems as reverse payments of cash" given the "great monetary value" that a no-AG agreement represents to the generic.[9] In February 2016, the First Circuit also "declined to limit *Actavis* to cash payments."[10]

While some may continue to argue that *Actavis* does not reach non-cash payments, courts appear to be dismissing the argument with increasing frequency.

What remains more elusive is what plaintiffs must allege in order to get past a motion to dismiss regarding the value of a non-cash payment. Some courts, while conceding that non-cash consideration may constitute a payment, have required plaintiffs to assign a monetary value to the non-cash portion of the settlement and a reliable foundation for that value before allowing claims to go forward.[11] Other courts, including the First Circuit, have concluded that plaintiffs must allege facts "sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment," but need not provide "precise figures and calculations" at the pleading stage. The First Circuit reasoned that "precise and particularized estimates" could "require evidence in the exclusive possession of the defendants, as well as expert analysis," placing a "nearly insurmountable" burden on plaintiffs.[12]

When Is a Payment "Large"?

Assuming that there is a payment, *Actavis* instructs courts to examine the size of the payment as a "workable surrogate" for a patent's weakness.

Part of the difficulty of addressing whether a payment is "large" is that it is an inherently relative analysis: large compared to what? Options range from the size of the relevant market, to annual sales of the pioneer or projected annual sales of the generic (likely to be smaller because generics are typically introduced at a fraction of the price of the pioneer drug), to profits of the pioneer or the generic, to any amount in excess of anticipated litigation costs.

The answer to this question has substantial ramifications for what payments are permissible. For example, a $25 million payment may be in excess of projected litigation costs and considered large if annual sales of a drug are $50 million, but small if annual sales of the drug are $5 billion.

The Supreme Court did not address the issue of what constitutes a "large" payment head-on and so courts and parties have been forced to look to context clues to fill in the gaps.

Plaintiffs have pointed to the Court's statement that the likelihood of anticompetitive effects depends on the payment's "scale in relation to the payor's anticipated future litigation costs" as the appropriate metric, though the same sentence also points to the payment's "size" as a separate factor.

Defendants have argued that "large" is to be determined in comparison to the value of the patent (either the benefit to the generic of invalidity of the patent or the benefit to the pioneer from continuing patent protection). This position finds some support in the Supreme Court's reliance on a study that showed that "patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market," which might suggest that the comparison should be to the generic's profits.[13]

Even so, at least one court has rejected that contention. That court reasoned, "[l]arge reverse payments that are not particularly large in relation to the value of the patent may show confidence in the patent, but if they represent payment *to avoid the risk of invalidation*, then they still run afoul of *Actavis*."[14]

In *FTC v. Cephalon*, the court agreed that "a reverse payment is sufficiently large if it exceeds saved litigation costs and a reasonable jury could find that the payment was significant enough to induce a generic challenger to abandon its patent claim," and denied defendants' summary judgment

motion.[15] The court cited evidence that the payments there were greater than the prospective generic manufacturers' expected profits if they won the litigation. The court concluded that the plaintiffs had presented sufficient evidence that a "reasonable jury could conclude the payments were aimed at delaying generic entry and that Defendants' justifications were pretextual."[16]

Some courts have adopted an even stricter standard. For example, the California Supreme Court concluded that any payment beyond avoided litigation costs and the value of any collateral benefits supports an inference that a settlement is anticompetitive.[17] Another district court denied a motion to dismiss even where the complainant did not allege that a payment was large in comparison to anything: the "existence of a reverse payment" and allegations that those payments were an overpayment for products and services rendered were considered sufficient.[18]

Another issue with which courts are grappling is whether to assess only the "unjustified" portion of the payment or the entire payment in determining whether it is large. One court concluded that it should look to the entire payment,[19] though a strong argument can be made that courts should instead consider only whether the "unjustified" portion of the payment is large. That is, insofar as the Supreme Court looks to the size of the payment as reliable evidence that the patent owner has serious doubts about the strength of its patents, one cannot make such an assumption to the extent the payment is justified.

What Justifies a Payment? Avoided Litigation Costs and Fair Value of Services

The Supreme Court in *Actavis* reasoned 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."

Moreover, in rejecting FTC's contention that reverse payment settlements should be deemed "presumptively unlawful," the Court reasoned that the "likelihood of a reverse payment bringing about anticompetitive effects" depends on, among other things, "its scale in relation to the payor's anticipated future litigation costs" and "its independence from other services for which it might represent payment."[20]

In other words, the Court recognized that reverse payments may be justified, and blessed two such justifications: litigation costs and fair value for services.

As to litigation costs, lower courts have coalesced around the idea that "avoided litigation costs are presumptively not large and unexplained under *Actavis,* and represent a *de facto* safe harbor."[21] And FTC, in its most recent order prohibiting reverse payment settlements, exempted settlement agreements providing for "saved future litigation expenses" up to $7 million, indexed for changes in the Producer Price Index for Legal Services.[22]

Courts have also followed the Supreme Court's edict that payments of fair value for other services rendered by the generic are lawful. However, it remains unsettled whether the plaintiff has the burden to prove payments exceeded fair value and were a sham, or the defendant has the burden of proving any payment was fair value for services to be provided.

Interestingly, the *Actavis* case itself involved allegations that the pioneer paid the prospective generic competitors through co-promote and backup manufacturing arrangements; the Court noted that FTC "contends [those] other services had little value."

In extending *Actavis* to California law, the California Supreme Court took the position that to show an illegal reverse payment the plaintiff must show that the consideration exceeds "the value of goods and services *other* than any delay in market entry provided by the generic challenger to the brand" in addition to litigation costs.[23]

Other courts, however, have held that even when services have been provided, a plaintiff raises factual disputes whether "the payments were reasonably necessary to achieve the procompetitive benefits," where evidence shows that (1) services were "unnecessary and unwanted," (2) the pioneer manufacturer was already receiving the services at a lower price, (3) the agreements did not meet the pioneer manufacturer's typical standards for supply agreements, (4) an intellectual property license was unnecessary, or (5) a product development agreement was projected to have a negative net present value for the pioneer.[24]

While some courts would require the plaintiff to show the portion of the payment attributable to the services exceeds the fair market value of those services,[25] other courts have put the burden on defendants, reasoning that

"establishing fair market value is just one of many possible defenses."[26]

The *In re Nexium* court reasoned, "[n]owhere in *Actavis* does the Supreme Court suggest that fair market value is a silver bullet against antitrust scrutiny." That court denied summary judgment based on evidence that showed side agreements were "lucrative" to the generic defendant and that they were negotiated "in conjunction with" the settlement, concluding that evidence "raises enough suspicions to support a reasonable inference that the Side Agreements were improper reverse payments."[27]

FTC and private plaintiffs have argued that any agreement for services contingent on the date of entry agreement should be illegal. And notably, the FTC order in *Cephalon* prohibits payments for services either "expressly contingent" on a patent settlement or agreed to within 30 days before or after executing the settlement.[28] This position, however, seems contrary to the Supreme Court's conclusion that payments that reflect compensation for other services are lawful, and its recognition that so long as the payments are for "fair value," the fact that they were reached in the context of a settlement agreement does not make those payments unlawful.

A Key Issue to Watch in 2016: Causation

Another interesting issue that has come to the front of the debate in 2016 is whether private plaintiffs must prove antitrust injury.

Because *Actavis* was brought by a government plaintiff under the FTC Act, defendants argue, the Supreme Court did not modify the standard required for a private plaintiff to show that the violation caused its injury in order to recover damages under the Sherman Act. While the issue of causation may seem largely procedural, it has significant practical implications. As one district court noted, requiring a private plaintiff to show causation "would act as a powerful brake to *Actavis's* potentially disruptive impact in the world of pharmaceutical patent litigation."[29]

Defendants argue that private plaintiffs, in order to show antitrust injury, must show that "the alleged antitrust violation was the cause in fact and the proximate cause of actual injury to [plaintiffs], which in [the reverse-payment] context means they must show that *if not* for the challenged settlement agreement, there *would have been* earlier entry of generics into the market."[30] Defendants distinguish *Actavis*, explaining that the Supreme Court only addressed the liability standard because FTC is not a private plaintiff and so does not need to show antitrust injury to recover damages.[31]

In general, courts recognize that "*Actavis* was brought by the FTC under § 5 of the FTC Act pursuant to its public enforcement powers, and sought only declaratory and prospective injunctive relief, not damages" and so "may not definitively answer whether the causation of damages can be shown without litigating the validity of [the] patents."[32] Given this omission, courts have struggled to reconcile the standard of liability set forth in *Actavis* with the traditional causation doctrine.

Some courts that have grappled with this issue have concluded that while the view that the Sherman Act requires private plaintiffs to show but-for causation to recover damages is "not an impossible interpretation of the case … I consider it dissonant with the decision's reasoning and on the whole a very unlikely interpretation."[33]

Another court rejected the argument that a plaintiff may only be injured if it shows total invalidity of the patent because the payment for a reduction in risk may itself be the anticompetitive effect. The court explained that:

> The value of the claim is a function of the parties' respective evaluations of risk and probability of success. … For example, in the context of a catastrophic personal injury claim, although a defendant might have formidable defense[s] to advance, in most instances the exposure created by the extent of the damages in and of itself creates an intrinsic settlement value for the claim. So too in this case, without reaching the ultimate question of the validity of the patents, the risk that the generic manufacturers might enter the marketplace and demonstrate a reasonable likelihood of success in voiding the patents has an economic consequence which plaintiffs contend was blunted by unlawful agreements preventing that form of competition.[34]

Other courts, however, have noted that FTC is only required to show that an agreement is "likely to cause injury," and that *Actavis*'s language "directly tracks" that standard, concluding that the issue of antitrust injury was not addressed by the Supreme Court.[35] For cases brought by private plaintiffs, on the other hand, the "causation requirement cannot be satisfied by using the size of the payment as a proxy for patent strength and the success of the underlying patent litigation."[36] To show causation a plaintiff would therefore have to show both that the settlement, not the underlying patents, prevented the entry of the generic

and that the generic company had the ability and intent to enter.[37]

The issue is now on appeal in both the First and Second Circuits.

Conclusion

So where does this leave pharmaceutical companies that want to settle Hatch-Waxman patent litigation without opening themselves to antitrust claims?

We can decipher some indications from the lower court decisions. For example, a payment may be justified under *Actavis* if it can be explained by avoided litigation expenses or by a payment for "fair value" for services. While courts appear to be comfortable valuing avoided litigation expenses, how courts will determine the "fair value" to attribute to services in order to determine whether a payment is unlawful is less clear. Courts are undertaking a fact-specific inquiry, looking to a variety of factors, including payments for comparable services by other industry players, the negotiation process as compared to processes employed for similar agreements, and the pioneer's need for the service.

In the future, who bears the ultimate burden to show the "fair value" of services may well become central to the outcome of litigation. Whether a private plaintiff must show causation in order to get damages under *Actavis* is also likely to have substantial practical implications. Pharmaceutical companies should continue to pay attention as courts grapple with these issues.

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1. The authors thank Meaghan Banks-Innes for her assistance.
2. FTC v. Actavis, Inc. ("*Actavis*"), 133 S. Ct. 2223 (2013). *Compare* FTC v. Watson Pharms., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012) (settlements generally "immune from antitrust attack"); In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1332-37 (Fed. Cir. 2008) (similar); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212-13 (2d Cir. 2006) (similar), *with* In re K-Dur Antitrust Litig., 686 F.3d 197, 214-18 (3d Cir. 2012) (settlements presumptively unlawful).
3. *Actavis*, 133 S. Ct. at 2237-38.
4. FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2014* (2016), *available at* https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf.
5. *Actavis*, 133 S. Ct. at 2234-37.
6. In re Lamictal Direct Purchaser Antitrust Litig., 18 F. Supp. 3d 560, 567 (D.N.J. 2014); In re Loestrin 24 FE Antitrust Litig., 45 F. Supp. 3d 180, 192 (D.R.I. 2014), *rev'd by* In re Loestrin 24 Fe Antitrust Litig., Nos. 14-2071, 15-1250, slip op. at 24, 33 (1st Cir. Feb. 22, 2016).
7. In re Aggrenox Antitrust Litig. ("*Aggrenox*"), 94 F. Supp. 3d 224, 242-43 (D. Conn. 2015); *accord In re Loestrin*, slip op. at 25-28 ("antitrust law . . . has consistently prioritized substance over form").
8. 791 F.3d 388 (3d Cir. 2015).
9. *Id.* at 404.
10. *In re Loestrin*, slip op. at 27.
11. United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA, Inc., 74 F. Supp. 3d 1052, 1069-71 (N.D. Cal. 2014); In re Lipitor Antitrust Litig., 46 F. Supp. 3d 523, 543-44 (D.N.J. 2014); In re Effexor XR Antitrust Litig., No. 11-5479 (PGS) (LHG), 2014 WL 4988410, at *19-23 (D.N.J. Oct. 6, 2014); In re Actos End Payor Antitrust Litig., No. 13-CV-9244 RA, 2015 WL 5610752, at *13 (S.D.N.Y. Sept. 22, 2015).
12. *In re Loestrin*, slip op. at 31-32 (quoting *Aggrenox*, 94 F. Supp. 3d at 244-45); *see also* In re Opana ER Antitrust Litig., No. 1:14-cv-10150, Memorandum Opinion and Order, p. 19-24 (N.D. Ill. Feb. 10, 2016).
13. *Actavis*, 133 S. Ct. 2223, 2235 (2013).
14. *Aggrenox*, 94 F. Supp. 3d at 247.
15. King Drug Co. of Florence, Inc., *et al.* v. Cephalon, Inc., 88 F. Supp. 3d 402, 417 (E.D. Pa. 2015).
16. *Id.* at 419.
17. In re Cipro Cases I & II ("*Cipro*"), 61 Cal. 4th 116, 154 (May 7, 2015).
18. In re Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 752-53 (E.D. Pa. 2014).
19. King Drug Co. of Florence, Inc., 88 F. Supp. 3d at 418 (E.D. Pa. 2015).
20. *Actavis*, 133 S. Ct. 2223, 2237 (2013).
21. *Aggrenox*, 94 F. Supp. 3d 224, 243 (D. Conn. 2015); *see also* In re Lipitor Antitrust Litig., 46 F. Supp. 3d 523, 546-47 (D.N.J. 2014); In re Lamictal Direct Purchaser Antitrust Litig., 18 F. Supp. 3d 560, 565, 570 (D.N.J. 2014).
22. FTC v. Cephalon, Inc., No. 2:08-cv-02141, Stipulated Order for Permanent Injunction and Equitable Relief ("Cephalon FTC Order"), p. 4 (E.D. Pa. June 17, 2015), *available at* https://www.ftc.gov/system/files/documents/cases/150617cephalonstip.pdf.
23. *Cipro*, 61 Cal. 4th 116, 151 (May 7, 2015) (emphasis original).
24. FTC v. Cephalon, Inc., 36 F. Supp. 3d 527 (E.D. Pa. 2014).
25. *Cipro*, 61 Cal. 4th at 152.
26. In re Nexium (Esomeprazole) Antitrust Litig., 42 F. Supp. 3d 231, 263 (D. Mass. 2014).
27. *Id.* at 264.
28. Cephalon FTC Order at 4.
29. *Aggrenox*, 2015 WL 4459607, at *9 (D. Conn. July 21, 2015).
30. *Id.* at *8 (emphasis original).
31. *Id.*
32. Time Ins. Co. v. AstraZeneca AB ("*AstraZeneca*"), 52 F. Supp. 3d 705, 710 (E.D. Pa. 2014).
33. *Aggrenox*, 2015 WL 4459607, at *9.
34. *AstraZeneca*, 52 F. Supp. 3d at 712.
35. In re Wellbutrin XL Antitrust Litig. ("*Wellbutrin*"), No. CV 08-2431, 2015 WL 5582289, at *25 (E.D. Pa. Sept. 23, 2015); *see also* In re Nexium (Esomeprazole) Antitrust Litig., No. 12MD-02409-WGY, 2015 WL 4720033, at *30 (D. Mass. Aug. 7, 2015) (the causation requirement on private antitrust plaintiffs "is to be distinguished from actions filed by the Federal Trade Commission under the FTC Act, which requires 'only that the government prove a defendant's action is '*likely to* cause' injury'") (emphasis original).
36. *Wellbutrin*, 2015 WL 5582289, at *25.
37. *Id.* at *26.