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Antitrust & Trade Regulation Report™

Principles of Antitrust Causation Are Alive and *Well[butrin]*: Why the Third Circuit Got It Right

EDITOR'S NOTE

THE SUPREME COURT'S DECISION IN *FTC v. ACTAVIS INC.* OPENED THE DOOR TO ANTITRUST LAWSUITS BASED ON "REVERSE PAYMENTS" — LARGE, UNEXPLAINED PAYMENTS TO GENERIC DRUGMAKERS TO SETTLE PATENT INFRINGEMENT CASES THAT COULD BE PAYOFFS FOR DELAYING A GENERIC VERSION OF A BRAND DRUG.

A SEPARATE APPEALS COURT DECISION, *IN RE WELLBUTRIN ANTITRUST LITIGATION*, COULD MAKE IT MORE DIFFICULT TO ASSIGN DAMAGES IN REVERSE PAYMENT CASES.

WILMERHALE ANTITRUST ATTORNEYS MARGARET O'GRADY AND PETER SPAETH EXPLORE HOW THE TWO OPINIONS CAN COEXIST.

BY MARGARET O'GRADY AND PETER SPAETH

Correctly interpreting Supreme Court precedent, the U.S. Court of Appeals for the Third Circuit made clear in its decision *In re Wellbutrin Antitrust Litigation* that, in a reverse payment case, to establish antitrust injury, private plaintiffs must show that it was more likely than not that a non-infringing generic product would have entered earlier absent the settlement agreement.

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The court rejected the plaintiffs' argument that injury could be shown by evidence of a "large, unexplained" payment alone. This is a straightforward application of the Clayton Act's "by reason of" requirement.

Several criticisms of the *Wellbutrin* decision misread *FTC v. Actavis Inc.* and ignore key differences between the plaintiff in *Actavis* (the Federal Trade Commission) and the plaintiffs in *Wellbutrin* (classes of direct and indirect purchasers).

Because *Wellbutrin* is a private antitrust action, the court's task differed from that of the *Actavis* court. *Actavis* considered only whether and in what circumstances reverse payment settlements violate the antitrust laws and had no reason to consider the requirement of causation in private cases. *Wellbutrin* does not represent a departure from *Actavis*, and should be viewed as a needed affirmation of the core principles of antitrust standing and causation. Indeed, courts are already correctly interpreting its take on antitrust standing.

1. The *Wellbutrin* Opinion In *Wellbutrin*, the Third Circuit affirmed the grant of summary judgment to defendant GlaxoSmithKline (GSK) in part because the plaintiffs — classes of direct purchasers and indirect purchasers — failed to establish a genuine dispute of fact as to whether GSK's actions delayed the launch of any generic version of Wellbutrin XL, an extended-release formula of a drug used to treat depression. (*In*

 ISSN 0003-6021

re Wellbutrin XL Antitrust Litig., 868 F.3d 132 (3d Cir. 2017).)

GSK had an exclusive license for Wellbutrin XL from Biovail (which was also a defendant in the antitrust litigation before settlement), and filed a new drug application (NDA) in 2002. After GSK filed its NDA, four generic drug manufacturers filed abbreviated new drug applications (ANDAs) with Paragraph IV certifications, alleging that the patent for Wellbutrin XL was invalid and not infringed. Biovail, joined by GSK, sued the generic manufacturers for patent infringement, triggering a stay that prevented generic entry until the patent suits were resolved or 30 months passed, whichever came first.

Then, in February 2007, GSK and Biovail entered into multiple settlement agreements with certain generic manufacturers that resolved the patent litigation and provided for generic entry in 2008, 10 years prior to patent expiry. (*Id*. at 150.)

The antitrust plaintiffs alleged that the settlement agreements involved reverse payments from GSK and/or Biovail to the generic manufacturers in the form of patent licenses, supply agreements, and most importantly, an agreement from Biovail and GSK that they would not launch an authorized generic for 180 days after generic entry, and that absent the settlement agreement, generic entry would have occurred even earlier than 2008.

Plaintiffs also alleged that GSK violated the Sherman Act by filing sham lawsuits and a baseless Food and Drug Administration citizen petition. The court analyzed the settlements in two parts. First, it analyzed whether the alleged reverse payments were subject to antitrust scrutiny. Second, it analyzed whether the plaintiffs suffered an antitrust injury because of the alleged reverse payments. *Actavis* bears on the first inquiry but not the second.

1.1. *Wellbutrin*'s Application of *Actavis* to Antitrust Liability The *Wellbutrin* court held that there was sufficient evidence to find that GSK made a ''large and unjustified'' reverse payment. (*Wellbutrin*, 868 F.3d at 169 (quoting *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013)).)

The Third Circuit first clarified that the settlement agreements were *not* beyond the reach of antitrust law solely because they involved an agreement not to launch an authorized generic, rather than payments of cash. The court also dispatched with the notion that the settlements were immune solely because they allowed the underlying patent litigation to continue.

The court found that GSK's payment — the agreement not to launch an authorized generic (no-AG agreement) — was ''large'' in that it was worth $233 million to the generic companies, and it ''could also be said to be unjustified in the sense of being unexplained'' because it was not tied to the merits of the underlying patent litigation. The court then concluded that the agreement ''implicate[d] the concerns identified in *Actavis*'' and must be reviewed under the rule of reason. (*Id.* at 163.)

1.2. *Wellbutrin*'s Analysis of Private Plaintiff Antitrust Standing The court next considered whether the plaintiffs had antitrust standing, and concluded that they did not. This inquiry focused on actual causation, not merely the ''risk'' of antitrust harm. The *Wellbutrin* court noted that ''antitrust standing is more properly viewed as an element of an antitrust claim that can be resolved at summary judgment.''

The court's standing analysis hinged on whether the but-for world was plausible — that is, what plaintiffs contend would have happened absent the no-AG agreement. *Wellbutrin* followed clear precedent that private antitrust plaintiffs must, at the summary judgment stage, present sufficient evidence from which a reasonable fact-finder could conclude that they suffered an injury that directly flowed from the alleged anticompetitive conduct. (15 U.S.C. § § 15, 26 (a suit may be brought by ''any person who shall be injured in his business or property *by reason of* anything forbidden in the antitrust laws'') (emphasis added); *Wellbutrin* 868 F.3d at 163 (citing *Ethypharm S.A. France v. Abbott Labs.*,707 F.3d 223, 232 n.15 (3d Cir. 2013).)

Thus, the court required evidence that it was ''more likely than not'' that generic entry would have occurred earlier in the but-for world, resulting in the plaintiffs paying lower prices for the drug. If earlier entry could not have occurred, no harm proximately flowed from the conduct at issue.

The court considered two potential avenues of earlier entry by Anchen (a prospective generic entrant) in the but-for world — through a license or as the result of the underlying patent litigation.

Regarding the license route, the court considered each of the plaintiffs' contentions that Anchen would have obtained a valid license from GSK's assignee, Andrx. The court found that the evidence did not support a finding that a license ''would'' have been obtained, only that it ''may'' have been, noting that the plaintiffs' scenario was not ''rooted in reality.'' (*Id*. at 167 (citing *Halsey v. Pfeiffer*, 750 F.3d 273, 287 (3d Cir. 2014) and other opinions holding that the summary judgment burden cannot be satisfied on ''speculation alone.'').)

As for the litigation scenario, the court examined the likelihood that Anchen would have prevailed in Andrx's patent suit, thus permitting non-infringing generic entry. The court considered the unrebutted expert analysis that Anchen had only a 20 percent chance of prevailing, complications arising from the party that had assigned the patent in the first place, and the lack of conclusive evidence that the patent was weak. The court found that ''[o]n this record, no reasonable jury could conclude that Anchen would have been more likely than not to prevail.'' (*Wellbutrin*, 868 F.3d at 167.)

The court held that the potentially ''large and unjustified'' nature of the alleged reverse payment at issue — which it had relied upon to find antitrust liability — was not sufficient for the plaintiffs to sustain their burden of causation on summary judgment. Unlike in the liability context, in the standing context, the court noted ''[t]hat there are multiple plausible ways to interpret the reverse payment in this case means that the payment alone'' was not dispositive. (*Id.* at 168.) Thus, the court affirmed summary judgment because the plaintiffs could not prove injury-in-fact.

2. Antitrust Liability and Antitrust Injury Are Separate and Distinct Requirements. *Wellbutrin* is grounded in the axiomatic proposition that antitrust liability and antitrust injury are separate and distinct inquiries. (*See, e.g., Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990) (''[P]roof of a[n antitrust] violation and of antitrust injury are distinct matters that must be shown independently.'') (quoting Phillip E. Areeda &

   ISSN 0003-6021

Herbert Hovenkamp, Antitrust Law ¶ 334.2c, at 330 (1989 Supp.).)

The existence of an antitrust violation requires only a general showing of harm to the competitive process. Section 5 of the FTC Act prohibits ''deceptive or unfair practices'' that cause or are ''likely to cause substantial injury to consumers.'' (15 U.S.C. § 45(a)(1)(n).) Thus, a government plaintiff need not prove that any particular party was injured. (*See Actavis*, 133 S. Ct. at 2236; *see also, e.g., In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 628 n.9 (E.D. Pa 2011).)

By contrast, the Clayton Act requires a specific showing by a private plaintiff that it suffered an injury-in-fact caused by the alleged anticompetitive conduct at issue. (*See, e.g., California v. American Stores Co.,* 495 U.S. 271, 296 (1990) (private plaintiffs must show the ''threatened loss'' or ''damages.'').)

The Supreme Court, as well as the Third Circuit, has reinforced this distinction several times. (*See, e.g. Zenith Radio Corp. v. Hazeltine Research, Inc*. 395 U.S. 100, 114 n.9 (1969) (explaining private plaintiff showing requirement under the Clayton Act); *see also Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc*., 429 U.S. 477, 486, 489 (1977) (explaining injury requirement as distinct from liability requirement); *see also Ethypharm S.A. France*, 707 F.3d at 232 (3d Cir. 2013) (listing factors enumerated by the Supreme Court to determine whether a complainant has antitrust standing); *see also Barton & Pittims, Inc. v. SmithKline Beecham Corp.,* 118 F.3d 178, 182 (3d. Cir. 1997) (considering private plaintiff antitrust injury and standing at summary judgment).)

2.1.1. Public Policy Supports Government, Private Distinction The difference in the requirements for government and private plaintiffs is rooted in the structure and purpose of the antitrust law. The federal government enforces the substantive antitrust laws directly while private plaintiffs' authority to challenge anticompetitive conduct comes from the Clayton Act, which imposes the additional burden that plaintiffs show they were injured ''by reason of'' the anticompetitive conduct at issue. (*See* 15 U.S.C. § 15.)

As the FTC explained in its brief as *amicus curiae* in *Wellbutrin*, ''[b]ecause the [FTC], along with the [Department of Justice], enforces the substantive antitrust laws directly, it need not show a specific injury. . .The distinction between public and private suits is intentional, reflecting the strong public law enforcement interest in allowing the government to redress conduct when 'the reasonably anticipated consequence' is a 'statutorily prohibited injury.' '' (Brief for the Fed. Trade Comm'n as Amicus Curiae at 20, *Wellbutrin*, 868 F.3d 132 (quoting 2 Areeda & Hovenkamp, Antitrust Law ¶ 303, at 61).)

The FTC made the same argument in *Nexium*, opining that ''the interest of the government is to 'prevent and restrain' violations of the antitrust laws along with the attendant social costs such violations can cause,'' while in contrast, ''[t]he interest of private plaintiffs is to remediate an injury they have suffered or may suffer.'' (Brief for the Fed. Trade Comm'n as Amicus Curiae at 10, *In re Nexium (Esomeprazole) Antitrust Litig.*, 777 F.3d 9 (1st Cir. 2015) (No. 15-200510) (''Nexium FTC Br.'') (internal quotations omitted).)

In short, the federal government's interest is to circumscribe the risk of harm to competition, while the private plaintiff's interest is remedial. The opportunity for private plaintiffs to recover treble damages is tempered by an additional burden of proof of standing and causation. The potential remedy was ''designed to compensate victims of antitrust violations for their injuries.'' (*Illinois Brick Co. v. Illinois*, 431 U.S. 720, 746 (1977).)

Indeed, it is common for courts to find that conduct was unlawful, but that the plaintiff nevertheless was not entitled to recover damages because it was not harmed by the conduct. (*See, e.g.,* Nexium FTC Br. at 8-9.)

2.2. *Actavis* Did Not Consider Antitrust Standing In *Actavis*, the FTC — a government agency not required to prove causation — challenged an alleged reverse payment from a brand pharmaceutical to a prospective generic entrant. The Supreme Court held that ''reverse payment settlements. . .can sometimes violate the antitrust laws'' and that courts should apply the ''rule of reason'' test when reviewing them. The Supreme Court noted that ''a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects[.]''

Accordingly, the court held that because ''the size of a reverse payment can provide a workable surrogate for a patent's weakness,'' it could be unnecessary for ''a court to conduct a detailed exploration of the validity of the patent itself'' for purposes of determining antitrust liability. The government did not need to prove the patentee would have lost the patent suit to show the settlement adversely affected competition.

Thus, at most, *Actavis* stands for the proposition that for *liability* purposes, it is not always necessary to litigate the likely outcome of the patent suit because ''an unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival.'' (*Actavis*, 133 S. Ct. at 2236-37.)

The *Actavis* court clearly did not address antitrust injury or suggest that it was modifying *sub silentio* standing requirements for private antitrust suits. This is especially salient given that the Supreme Court appears ''increasingly wary'' about private antitrust enforcement — there is no basis to believe that it would have suddenly eased the standing requirement for private reverse-payment plaintiffs, without clearly announcing it was doing so. (J. Thomas Rosch, Comm'r, Fed. Trade Comm'n, Striking a Balance? Some Reflections on Private Enforcement in Europe and in the United States, Remarks Before the Int'l Chamber of Commerce Annual Meeting 17 (Sept. 24, 2008).)

3. Differences Between *Actavis* and *Wellbutrin* Plaintiffs state in their petition for rehearing *en banc* that the *Wellbutrin* opinion ''undermine[d]'' *Actavis*, because it ignored *Actavis*'s directive that ''the size of the unexplained payment can provide a workable surrogate for a patent's weakness.'' (*See* Plaintiffs' Pet. For Rehearing and Rehearing en banc, *In re Wellbutrin*, 868 F.3d 132 (3d Cir. 2017) (''Rehearing Pet.'').)

However, as discussed above, the court in *Actavis* did not consider private plaintiffs' antitrust standing, and the *Wellbutrin* court took ''large and unjustified'' factor into consideration when it held that the alleged reverse payments merited antitrust scrutiny in the first place.

The amicus brief filed by the law, economics, and business professors likewise states that ''*Actavis*'s teachings'' are ''just as relevant for causation as for li-

ability.'' (Brief for 58 Economics and Law Professors as Amicus Curiae at 8, *Wellbutrin*, 868 F.3d 132 (''Law Professors Br.'').)

The professors note that ''in analyzing antitrust standing, the panel . . . offered an opinion inconsistent with Supreme Court case law.'' However, their analysis does not grapple with the question of how *Wellbutrin*'s standing analysis can contradict *Actavis*, when *Actavis* did not conduct any standing analysis.

3.1 Risk Aversion Theory Debates about the ''risk aversion'' theory similarly lack a recognition of how the differences between *Actavis* and *Wellbutrin* belie that the latter contradicts the former. By way of background, a group of antitrust economists put forth a ''risk aversion'' theory in an amicus brief in support of the defendants in *Wellbutrin*. They argued that the size of an alleged reverse payment is not always a suitable proxy for the weakness of the underlying patent, because risk-averse firms could rationally decide to make a ''large'' reverse payment that does not tightly correlate to the unlikelihood of the patent-holder prevailing in the underlying patent suit. In other words, the ''risk aversion'' theory presents another explanation for a ''large'' payment besides patent weakness.'' (Brief for the American Antitrust Institute as Amicus Curiae at 11, *Wellbutrin*, 868 F.3d 132.)

The *Wellbutrin* court favorably referenced the ''risk aversion'' theory when it considered whether the size of the alleged reverse payments could alone establish antitrust injury. Plaintiffs and their *amici* interpreted the *Wellbutrin* court as impermissibly resuscitating an argument that ''*Actavis* explicitly rejected'' and ''substitute[ing] an inference of 'risk aversion' for ''the inference of patent weakness from a large reverse payment.'' (Brief for the Nat'l Assoc. of Chain Drug Stores as Amicus Curiae at 11, *Wellbutrin*, 868 F.3d 132; Rehearing Pet. at i; *see also* Law Professors Br. at 5.)

However, the *Wellbutrin* court only referred to the ''risk aversion'' theory later in its opinion, when it was considering whether the plaintiffs could prove antitrust causation. (*Wellbutrin* 868 F.3d at 168.) The court did not credit the risk aversion theory when it decided antitrust liability under *Actavis* — specifically, whether the alleged reverse payments were ''large and unjustified'' such that they created the risk of competitive harm, finding that the plaintiffs could not establish antitrust causation based on the size of the alleged reverse payment, in part because the payment's size did not necessarily have a direct correlation to the likelihood of earlier generic entry in the but-for world.

4. *Wellbutrin* Follows in *Nexium*'s Footsteps The U.S. District Court for the District of Massachusetts' opinion in *Nexium* was the first to interpret *Actavis*, and the court described its task as putting ''the Supreme Court's holding into practice.'' (*In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 240 (D. Mass 2014), *aff'd* (842 F.3d 34 (1st Cir. 2016)).)

The plaintiffs in *Nexium* were classes of direct purchasers, end payors, and indirect purchasers that challenged alleged reverse payment settlements between a brand manufacturer (AstraZeneca) and generic companies (Teva and Ranbaxy). The district court treated liability and injury as separate requirements, noting that ''at the summary judgment stage. . .the plaintiffs bear the burden of evincing evidence that would enable a reasonable jury to find each core element of an antitrust claim — including causation.'' This characterization of causation as a ''core element'' was echoed by the *Wellbutrin* court. (*See Nexium*, 42 F. Supp. 3d at 287; *Wellbutrin*, 868 F.3d at 164 (''[A]ntitrust standing is more properly viewed as an element of an antitrust claim that can be resolved at summary judgment.'').)

The court performed robust evidentiary analyses to determine whether there was sufficient evidence in the record that lawful and earlier generic entry would have occurred in the but-for world, and thus the plaintiffs suffered an injury-in-fact. (*Nexium*, 42 F. Supp. 3d at 266 (''Plaintiffs have offered little evidence in support of their complicated, multi-step proposition that the FDA would have approved Ranbaxy's generic Nexium any earlier than May 2014 in the absence of this settlement agreement.'').)

After the district court's *Nexium* decision, the case went to trial and the jury found that although plaintiffs proved an antitrust violation in the form of a large and unjustified reverse payment, they did not prove that they suffered an antitrust injury. The judge summarized the questions for the jury: ''Just making a deal. . .is not enough for liability [;] there has to be a harm.'' (*Nexium*, 842 F.3d 34 at 50.) The plaintiffs appealed the verdict based on what they claim was clear error in the jury instructions, essentially arguing that they did not have to prove causation.

The FTC filed an amicus brief urging the U.S. Court of Appeals for the First Circuit to make it explicit that ''in an antitrust case, violation and injury-in-fact are distinct analyses.'' (*Nexium* FTC Br. at 8.) Agreeing with the FTC, the First Circuit roundly rejected the plaintiffs' argument that the jury instructions were improper, and reiterated the difference between liability and injury.

The First Circuit agreed to ''provide greater clarity'' on this point, and held plainly that ''the plaintiffs may have obscured the clear law that, as private plaintiffs seeking damages, they must prove not only an antitrust violation but also an antitrust injury that allows recovery of damages.'' The court went on to explain that because plaintiffs derive their authority from the Clayton Act, they must show ''actual, quantifiable damages.'' (*Nexium*, 842 F.3d 34 at 60.)

In *Wellbutrin*, the Third Circuit followed the First Circuit's lead, and engaged in a robust causation analysis that was clearly separate from the question of liability. Admittedly, what the *Wellbutrin* court did differently than the district court in *Nexium* was to discuss the size of the payment *at all* when determining lack of antitrust causation. However, the *Wellbutrin* court did so only to point out that the alleged payment's large size was not dispositive to the causation analysis.

The *Nexium* court did not mention *Actavis* anywhere in its discussion of antitrust injury. Indeed, the *Wellbutrin* court cited approvingly to *Nexium* when it determined that Anchen (a prospective generic entrant) would have been unable to enter the market lawfully anyway, and thus was not injured by the alleged reverse payments.

The *Wellbutrin* plaintiffs, like the *Nexium* plaintiffs before them, instead advocated for a conflation of the two inquiries that is contrary to the law. The *Wellbutrin* court rightly rejected that effort. Other post-*Actavis* opinions have likewise demonstrated a robust separation of the liability and causation elements, applying *Actavis* solely to the former.

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5. Conclusion *Wellbutrin* affirmed the meaning of the Clayton Act's ''by reason of'' requirement as separate from the question of antitrust liability. Antitrust law has always rightfully demanded proof of causation to permit recovery from private plaintiffs, whereas government actions are focused more on the likely consequences to the public, to curb potentially anticompetitive behavior. Criticisms of *Wellbutrin* that accuse it of contradicting *Actavis* reflect a misreading of the opinion and of *Actavis* and its progeny and a disregard of Clayton Act's ''by reason of'' requirement.

The opinion is *In re Wellbutrin Antitrust Litigation*, 3d Cir., Nos. 15-2875/3559/3591/3681/3682, 8/8/17.

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