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NOTE

Causation in Reverse Payment Antitrust Claims

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Abstract. Following the U.S. Supreme Court's 2013 holding in *FTC v. Actavis, Inc.* that antitrust liability can attach to reverse payment patent settlements, courts have diverged about how to determine whether private parties who prove that such an agreement violates antitrust law are entitled to any relief. Unresolved issues about the private plaintiff causation requirement are likely to recur as more courts reach the issue.

This Note identifies two approaches to causation. Under a narrow approach adopted by the First and Third Circuits, private plaintiffs are required to piece together precise details about what would have happened if the patent litigation had not settled—including details the Supreme Court expressly held were usually unnecessary to pin down in government enforcement cases. In contrast, the California Supreme Court and several federal district courts have drawn a broader causal inference. For these courts, causation exists whenever a challenged settlement delays competition *in expectation*. This Note explains why the broader approach better aligns with the rationales undergirding private enforcement of the prohibition against certain reverse payment settlement agreements.

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Introduction

In a landmark 2013 decision, the Supreme Court settled an important issue at the forefront of the intersection between intellectual property and antitrust law. Resolving a question that had split the circuits, the Court held in *FTC v. Actavis, Inc.* that one particular way of settling a patent dispute—which had been used primarily within the pharmaceutical industry—could, under some circumstances, violate the antitrust laws.[1] As Justice Breyer explained in his opinion for the Court, the antitrust claim is based on the following series of events:

> Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a "reverse payment" settlement agreement. And the basic question here is whether such an agreement can sometimes unreasonably diminish competition in violation of the antitrust laws.[2]

The Court answered this question in the affirmative, instructing lower courts that the agreements *could* be illegal and that courts must apply the antitrust "rule of reason" to determine whether any particular agreement is in fact illegal.[3] This holding constituted a middle ground: The defendants had argued that these agreements should essentially be treated as per se legal, while

1. *See* 133 S. Ct. 2223, 2227, 2238 (2013).

2. *Id.* at 2227.

3. *See id.* at 2227, 2237. The "rule of reason" is "an exercise of burden-shifting" that comprises a series of discrete steps. *See* Michael A. Carrier, *The Real Rule of Reason: Bridging the Disconnect*, 1999 BYU L. REV. 1265, 1268. First, "the plaintiff must show a significant anticompetitive effect resulting from the restraint." *Id.* If the plaintiff does so, then "the burden shifts to the defendant to demonstrate a legitimate procompetitive justification for the restraint." *Id.* If the defendant does so, the plaintiff bears the burden at the next stage "to show either that the restraint is not reasonably necessary to achieve the objectives of the restraint or that the objectives could be achieved by alternatives 'less restrictive' of competition." *Id.* at 1268-69 (footnote omitted). Plaintiffs who carry this burden prevail; the claims of those who do not are subject to a balancing approach that weighs "the restraint's anticompetitive and procompetitive effects." *Id.* at 1269; *see also* 7 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 1502, at 398-99 (4th ed. 2017) [hereinafter AREEDA-HOVENKAMP] (laying out a similar inquiry but collapsing it into three discrete steps). The "rule of reason" contrasts with the "per se" approach, under which certain agreements are condemned because they fall within "a class of conduct, such as price fixing, which is then said to be intrinsically or 'per se' unlawful." *See* 7 AREEDA-HOVENKAMP, *supra*, ¶ 1500, at 387.

the Federal Trade Commission (FTC) had pushed the Court to treat them as presumptively unlawful[4]—something the "rule of reason" stops short of doing.

This Note identifies a split in approaches that has arisen in the years since *Actavis* with respect to private antitrust challenges to these agreements (that is, cases brought by private individuals, not by a government agency like the FTC). This Note demonstrates why one such approach is more faithful to *Actavis* and to the policy goals underlying antitrust enforcement in this area. One reason courts have had this room to diverge from each other is that private antitrust cases require the plaintiff to show not only that there was an antitrust violation—which was the focus of the *Actavis* decision because the FTC need only show a violation to prevail—but also that the plaintiff has suffered a remediable injury.[5] To understand the split and why it matters, it's necessary to understand a bit more about the antitrust violation the Court assessed in *Actavis*.

The problem with reverse payment settlement agreements is that they may (but need not always) amount to "pay-for-delay."[6] Unlike a typical settlement, the payment in this type of settlement flows in reverse: The patent plaintiff, which stands to lose only its own litigation expenses by proceeding to trial, is paying a large sum of money to a company it claims infringes its patent, as a condition of dismissing its own lawsuit.[7] What the plaintiff gets in exchange is a promise that the alleged infringer will drop any counterclaims and wait to enter the market until sometime between the time of settlement and the expiration of the patent—a promise that a valid, infringed patent

4. *See Actavis*, 133 S. Ct. at 2230, 2234, 2237; Brief for Respondent Solvay Pharmaceuticals, Inc. at 9, *Actavis*, 133 S. Ct. 2223 (No. 12-416), 2013 WL 648743.

5. *See* 2A AREEDA-HOVENKAMP, *supra* note 3, ¶ 335a, at 76-77 (4th ed. 2014). This requirement exists because private antitrust enforcement simultaneously serves two goals: deterrence and compensation. On the deterrence side, private plaintiffs are "not the attorney general or even a full-fledged 'private attorney general,'" although they do have an important "role in enforcing antitrust law—enforcement purposefully stimulated by the lure of treble damages." *See id.* ¶ 337b, at 108. But only private plaintiffs who have suffered injury that can be compensated by the lawsuit can recover damages. *See id.* ¶ 337b, at 108 & n.18 (citing Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 485-86 (1977)). An analogy might be drawn to other contexts where private enforcement of public rights is limited to plaintiffs who have suffered compensable injury, such as civil rights actions brought under 42 U.S.C. § 1983. *See* Carey v. Piphus, 435 U.S. 247, 254-57 (1978) (explaining that "the basic purpose of a § 1983 damages award should be to compensate persons for injuries caused by the deprivation of constitutional rights").

6. *See Pay-for-Delay: When Drug Companies Agree Not to Compete*, FED. TRADE COMMISSION, https://perma.cc/JND9-FYFM (archived Feb. 24, 2018). *See generally* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006) (identifying antitrust concerns with pay-for-delay agreements).

7. *See Actavis*, 133 S. Ct. at 2227.

would give it the right to extract in the first place.[8] The problem is that had the lawsuit not been settled in this fashion, the patent might have been shown to be invalid or not infringed, the alleged infringer might have entered the market "at risk" without a final adjudication on validity, or the parties might have reached a different settlement that did not restrain competition—all of which would have allowed the alleged infringer to enter the market sooner and introduce a competing product.[9] That shift from a market potentially monopolized by the patentee to one competitors can freely enter could drastically lower consumer prices.[10] And one of the primary concerns of antitrust law is stamping out any agreement between competitors the likely result of which is an increase in consumer prices.[11]

As a result of the Food and Drug Administration (FDA) regulatory regime, "[a]pparently most if not all reverse payment settlement agreements arise in the context of pharmaceutical[s] . . . , and specifically in the context of suits brought under statutory provisions allowing a generic drug manufacturer (seeking speedy marketing approval) to challenge the validity of a patent owned by an already-approved brand-name drug owner."[12] Indeed, there are good reasons to suspect that such agreements occur almost exclusively in this context.[13] Here, a pay-for-delay antitrust claim translates into the allegation

8. *See* 1 HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 16.01, at 16-3 to -4 (3d ed. 2017) (indicating that a company certain it is holding a valid and infringed patent "would have no incentive whatsoever to pay another firm to stay out of the market" because "[i]t could exclude without paying anything at all").

9. *See In re* Opana ER Antitrust Litig., 162 F. Supp. 3d 704, 720-21 (N.D. Ill. 2016) (listing possibilities in the absence of a challenged reverse payment settlement); Michael A. Carrier, *Payment After* Actavis, 100 IOWA L. REV. 7, 10 (2014) (explaining that the antitrust concern with a reverse payment settlement is that a brand-name firm has "convey[ed] a type of consideration not otherwise available to a generic" manufacturer).

10. *See* FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010), https://perma.cc/5V5B-QUE6.

11. *See* 11 AREEDA-HOVENKAMP, *supra* note 3, ¶ 1902a, at 232 (3d ed. 2011) ("Horizontal agreements are antitrust's most 'suspect' classification . . . . The main threat of horizontal agreements is that they can enable participants to reduce the output of goods in some market, thus causing higher prices, inefficient substitutions, and the resultant losses in consumer welfare.").

12. *See Actavis*, 133 S. Ct. at 2227.

13. The "unique rules" relevant to pharmaceutical regulation come from the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of the U.S. Code), usually referred to as the Hatch-Waxman Act. *See* 1 HOVENKAMP ET AL., *supra* note 8, § 16.01[A], at 16-5. Hatch-Waxman "attempted to balance the branded drug manufacturers' innovation incentives against the need to facilitate market entry by manufacturers of equivalent generic products." *Id.* One way the Act seeks to promote generic entry is by allowing a generic pharmaceutical challenger to obtain FDA approval through an abbreviated process if, in its application, it "asserts that the relevant patent is invalid or not

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that a brand-name drug owner has illegally reached an agreement with its potential generic competitor to delay generic entry into the market.[14] The cost to consumers of such a delay can be massive: The FTC estimated in one study that consumers save an average of 77% on drug costs after a generic market matures and that pay-for-delay agreements wind up costing U.S. consumers a total of $3.5 billion per year.[15]

By holding in *Actavis* only that reverse payment settlement agreements may, under some circumstances, amount to illegal agreements in restraint of trade, the Supreme Court kicked the can down the road on many issues that arise in determining whether an agreement actually violates the antitrust laws. Issues that have received attention from courts and scholars include, for example, whether certain noncash provisions in a settlement agreement should count as reverse *payments*.[16] One set of questions that has come up several times in courts but to which little scholarship has been devoted, however, is how to approach the unique issues that arise when a claim is

infringed." *See id.* at 16-7. Submitting this "Paragraph IV certification" guarantees one or more first-filing generics a 180-day exclusivity period in which no other generics can enter the market—even if the first filers are unsuccessful in the patent challenge. *See id.* at 16-9; *see also* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2016) (Paragraph IV); *id.* § 355(j)(5)(B)(iv) (180-day exclusivity provision). This exclusivity period "offers the potential for collusive settlement arrangements between brands and generics": The restrictions on entry by anyone other than the first filers "mean that paying off a single competitor may prevent all competition, at least for a time." *See* 1 HOVENKAMP ET AL., *supra* note 8, § 16.01[A], at 16-10; *id.* § 16.01[D], at 16-24 n.100. Outside this regulatory context, it might be foolish for a patentee to think that it can actually foreclose competition by entering into a reverse payment settlement; it could expect a flood of challenges to its patent from those who hope to extract similar settlements. *See Actavis*, 133 S. Ct. at 2235. Under Hatch-Waxman, by contrast, the patentee may know that no follow-on challengers would have enough skin in the game to initiate the challenge because, as a result of not having filed first, those follow-on challengers will be unable to compete during the lucrative 180-day exclusivity period. *See* 1 HOVENKAMP ET AL., *supra* note 8, § 16.01[D], at 16-24 n.100, 16-35 (noting that under Hatch-Waxman, "first-filing generics often receive the 'vast majority' of their profits during the 180-day period" (quoting *Actavis*, 133 S. Ct. at 2229)).

14. *See* Hemphill, *supra* note 6, at 1616 (describing the brand-name drug company's "incentive to pay to neutralize . . . potential competition").

15. *See* FTC, *supra* note 10, at 2, 8; *see also id.* at 8 ("[A] generic market typically matures about one year after the first entrant comes on the market.").

16. *See, e.g.*, Am. Sales Co. v. Warner Chilcott Co. (*In re* Loestrin 24 FE Antitrust Litig.), 814 F.3d 538, 549-53 (1st Cir. 2016) (holding that *Actavis* applies to "non-monetary reverse payments"); King Drug Co. of Florence v. Smithkline Beecham Corp. (*Lamictal*), 791 F.3d 388, 403-10 (3d Cir. 2015) (holding that a patentee's agreement "not to produce an authorized generic" of a drug should be evaluated under the *Actavis* rubric); Carrier, *supra* note 9, at 35-47 (describing various forms of reverse payment); C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 682-85 (2009) (similar); *see also* 1 HOVENKAMP ET AL., *supra* note 8, § 16.01[D], at 16-22 to -48 (collecting and assessing court decisions).

brought by a private party—as many are.[17] These issues warrant particularly close attention as courts begin to decide not only whether a private plaintiff has even stated a claim that survives a motion to dismiss—something several courts have already done in the wake of *Actavis*—but also what a plaintiff will ultimately need to show to win at trial.

Government agencies like the FTC can win an antitrust case by demonstrating that the defendants have violated some antitrust law[18]—here, the Sherman Act's "prohibition of 'restraint[s] of trade or commerce.'"[19] As the leading antitrust treatise explains, private parties need to show (1) such a violation *plus* (2) that they have "antitrust standing" to recover as a result of the violation.[20] Private party claims brought by drug purchasers (such as pharmacies, insurance companies, and end users) in the wake of *Actavis* therefore raise some issues unique to the private enforcement context; as this Note explains in more detail, these issues are best understood as falling under the causation requirement for antitrust standing.

Courts have diverged in their approaches to assessing causation for reverse payment settlement claims since *Actavis*. One approach subjects private plaintiffs to substantial requirements the government does not face, including the type of "patent analysis and litigation" the Court held unnecessary for proving an antitrust violation in *Actavis*.[21] Decisions of the First and Third Circuits have endorsed this narrow approach, as has a federal district judge's decision to bifurcate a trial in a case that was ultimately settled midway through the presentation of evidence.[22] But courts in another camp have imposed less onerous requirements on private plaintiffs. This broader approach has been adopted by the California Supreme Court and three federal

17. *See* Brief for Respondent Solvay Pharmaceuticals, Inc., *supra* note 4, at 40 (explaining that each FTC enforcement case is "followed by droves of private-plaintiff lawsuits" and that private plaintiffs have also challenged reverse payment agreements the FTC "never pursued"); *see also* 1 HOVENKAMP ET AL., *supra* note 8, § 16.01[D], at 16-22 to -48 (collecting cases); *infra* Part II (discussing several of these cases).

18. *See* 2A AREEDA-HOVENKAMP, *supra* note 3, ¶ 335a, at 76 (4th ed. 2014).

19. *Actavis*, 133 S. Ct. at 2227 (alteration in original) (quoting 15 U.S.C. § 1); *see also* Sherman Act, ch. 647, 26 Stat. 209 (1890) (codified as amended at 15 U.S.C. §§ 1-7 (2016)).

20. *See* 2A AREEDA-HOVENKAMP, *supra* note 3, ¶ 335a, at 76-77 (4th ed. 2014) (capitalization altered). For background on the Areeda-Hovenkamp treatise, see Rebecca Haw Allensworth, *The Influence of the Areeda-Hovenkamp Treatise in the Lower Courts and What It Means for Institutional Reform in Antitrust*, 100 IOWA L. REV. 1919 (2015).

21. *See* Ian Simmons et al., *Viewing* FTC v. Actavis *Through the Lens of Clayton Act Section 4*, ANTITRUST, Fall 2013, at 24, 26; *see also Actavis*, 133 S. Ct. at 2236.

22. *See In re* Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 163-70 (3d Cir. 2017); Am. Sales Co. v. AstraZeneca LP (*In re* Nexium (Esomeprazole) Antitrust Litig.), 842 F.3d 34, 59-64 (1st Cir. 2016); Apotex, Inc. v. Cephalon, Inc., 255 F. Supp. 3d 604, 612-14 (E.D. Pa. 2017); *see also infra* Part II.A.

district judges,[23] and it gains additional support from a Second Circuit decision.[24]

After identifying and describing the arguments advanced by each of these two camps, this Note takes the position that the latter has the better argument. Unlike two prior commentaries that address this issue,[25] this Note takes a comprehensive look at the arguments and court decisions in support of both sides. It then argues that the causation requirement should not generally be fatal to private plaintiff recovery for reverse payment claims—something the narrow approach all but guarantees. While there are indeed certain pieces of proof these plaintiffs will need to amass that the FTC would not, this Note argues that courts adopting the narrow approach are requiring far more of plaintiffs than they should.

This Note proceeds in three Parts. Part I provides background on the two relevant components of a private antitrust claim alleging an illegal reverse payment settlement agreement. Part II then identifies a split in authority about how to tie those two components together into a winning claim. Part III evaluates these opposing approaches, concluding that doctrine and policy require a relatively modest causation inquiry that does not carry with it the burdens imposed by the narrow approach.

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23. *See In re* Opana ER Antitrust Litig., 162 F. Supp. 3d 704, 720 (N.D. Ill. 2016); *In re* Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 239-41 (D. Conn. 2015); *In re* Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 754-57 (E.D. Pa. 2014); *In re* Cipro Cases I & II, 348 P.3d 845, 859, 863-64, 870 & n.19 (Cal. 2015); *see also infra* Part II.B.

24. *See* United Food & Commercial Workers Local 1776 v. Takeda Am. Holdings (*In re* Actos End-Payor Antitrust Litig.), 848 F.3d 89, 100-01 (2d Cir. 2017).

25. At least two commentaries, both authored by practitioners from private defense-side law firms, have focused on the issue of private plaintiffs' burden of proof in reverse payment settlement antitrust cases. The first of these, written soon after *Actavis*, briefly laid out key elements of the argument ultimately adopted by one of the two camps of courts—including the idea that "some form of patent analysis and litigation is necessary in private actions post-*Actavis*"—but did not include a discussion of any court opinions addressing the issue (the most relevant of which had not been written yet). *See* Simmons et al., *supra* note 21, at 25-26. The second did identify some of the court decisions discussed in this Note and describe them as taking divergent approaches, though it laid out only briefly what courts had done and proceeded to stake out a position that differs substantially from the approach this Note advocates. *See* Peter Thomas et al., *The Causation Question Left Unanswered by* Actavis, LAW360 (Dec. 5, 2016, 12:36 PM EST), https://perma.cc/PF8V-3LXP ("This article argues that private plaintiffs seeking monetary damages must allege, and eventually prove by a preponderance of the evidence, patent invalidity or non-infringement in order to succeed on a claim for damages under Actavis.").

I. *Actavis* and Private Party Standing

This Part first describes how an antitrust violation is shown for a reverse payment settlement. It next explains the causation requirement for private plaintiff recovery.

A. Nature of the Anticompetitive Harm That Flows from a Reverse Payment Settlement

After summarizing why reverse payment settlement agreements can be anticompetitive, this Subpart highlights how the *Actavis* Court's holding turns on a probabilistic view of patent validity.

1. The problem addressed in *Actavis*

A reverse payment settlement poses a dilemma for antitrust law because it sits between two extremes: At one end is an agreement that is per se legal under the antitrust laws; at the opposite end, one that is per se illegal.[26]

A reverse payment settlement agreement would be per se legal if the only market entry it constrained would infringe a valid patent. For example, suppose a patentee has sued a competitor, claiming that the competitor has infringed its patent. If it turns out, through the course of the litigation, that there is overwhelming evidence that the patentee will prove that the patent is valid and infringed and will therefore win the lawsuit, the parties may settle. As part of the settlement, the patentee could insist that the infringer wait to enter the market until the patentee's valid patent has expired. The patentee's right to exclude any competitor whose product infringes its valid patent until that patent expires is the hallmark of owning and exercising patent rights, and antitrust law does not stand in the way of the patentee taking full advantage of this government-granted monopoly.[27]

At the other extreme, entering into the same settlement without a valid patent at the heart of the deal would be per se illegal under the antitrust laws:

26. A large body of scholarship, both pre- and postdating *Actavis*, analyzes the anticompetitive potential of reverse payment settlements. *See generally* 1 HOVENKAMP ET AL., *supra* note 8, § 16.01 (discussing antitrust challenges to reverse payment settlements); Carrier, *supra* note 9 (analyzing reverse payment issues that remain unresolved after *Actavis* and proposing an overarching test); Aaron Edlin et al., *The* Actavis *Inference: Theory and Practice*, 67 RUTGERS U. L. REV. 585 (2015) (discussing *Actavis* and providing a roadmap for its implementation); Hemphill, *supra* note 6 (analyzing antitrust concerns with pay-for-delay agreements); Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's* Actavis *Decision*, 15 MINN. J.L. SCI. & TECH. 3 (2014) (commenting on *Actavis*).

27. *See* 1 HOVENKAMP ET AL., *supra* note 8, § 1.03[B], at 1-17 ("[A]ntitrust will be concerned not with the legitimate exercise of an intellectual property right granted by the government, but with efforts to *expand* the scope of that right . . . .").

Once the patent is stripped out of the equation, the settlement in question is no different from a horizontal market allocation. The seminal case on horizontal market allocations, *Palmer v. BRG of Georgia, Inc.*,[28] illustrates why antitrust law condemns as automatically anticompetitive these agreements between competitors to divide up the market along some dimension like geographic space. In that case, two companies that provided bar exam prep materials reached an agreement that the Court held illegally restrained trade in violation of section 1 of the Sherman Act.[29] The companies, BRG and HBJ, had competed "intense[ly]" between 1977 and 1979 to enroll students planning to take the Georgia bar exam.[30] But in 1980, the two entered into an agreement under which "HBJ would not compete with BRG in Georgia and . . . BRG would not compete with HBJ outside of Georgia."[31] Unsurprisingly, this reduction in competition led to an immediate price increase for bar prep courses.[32] Reiterating the rule that "agreements between competitors to allocate territories to minimize competition are illegal," the Court held that the 1980 agreement was "unlawful on its face."[33]

The patent settlement agreement described above as per se legal transforms into a per se illegal agreement if the valid, infringed patent is stripped out of the equation. Setting aside the patent, the parties' settlement means that they have agreed that one company (the defendant in the patent suit, typically a generic drug producer in the cases where these antitrust claims arise[34]) will wait to enter the market until some future date. This lets the other party to the settlement agreement (the plaintiff in the patent suit, typically a brand-name drug producer) dominate the market until that date. That is an agreement between competitors to allocate the market based on time, which is just as illegal as the geographic allocation condemned in *Palmer*.[35]

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28. 498 U.S. 46 (1990).

29. *See id.* at 47, 49-50 (per curiam) (citing 15 U.S.C. § 1).

30. *See id.* at 47.

31. *Id.*

32. *See id.* at 49.

33. *Id.* at 49-50 (citing United States v. Topco Assocs., 405 U.S. 596, 608 (1972)).

34. *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013).

35. *See* 12 AREEDA-HOVENKAMP, *supra* note 3, ¶ 2030c, at 222 (3d ed. 2012) (identifying as an "important element" of horizontal market division the right of one competitor "to restrict the way that a rival expands or innovates"); *cf. Actavis*, 133 S. Ct. at 2227 (suggesting that the "agreement not to compete" at issue in *Palmer* raised issues analogous to those raised by reverse payment settlements); Carrier, *supra* note 9, at 14 ("Settlement agreements by which brands pay generics not to enter the market threaten dangers similar to territorial market allocation. But instead of allocating geographic space, in which the parties reserve for themselves particular territories, they allocate time."). The FTC identified horizontal market allocation as the basis for rigorous antitrust scrutiny of reverse payment settlements in a 2003 order, explaining

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The difficulty in assessing the antitrust implications of a reverse payment settlement is that as of the date of the agreement, there is some probability that the patent being asserted is valid and infringed, and some probability that it is not.[36] This uncertainty means that—at least as of the date of the settlement agreement—there is some chance that the agreement was just like a valid exercise of patent rights and some chance that the agreement was just like a horizontal market allocation. But this does not mean that the antitrust claim that the settlement was anticompetitive is hopelessly indeterminate, for one other feature of the agreement is available to the adjudicator:

> An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness.[37]

This makes sense: A patentee would not rationally agree to make a large payment just to keep a competitor out of the market during the life of its patent unless it feared that it could lose the patent case and therefore face earlier entry by that competitor. The *Actavis* Court therefore held that these settlement agreements could sometimes violate antitrust law: The "risk of significant anticompetitive effects" in these settlements flows from "reverse payment[s]" that are "large and unjustified."[38] Because the large, unjustified

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that "an allocation of time is analogous to an allocation of geographic space," Schering-Plough Corp., 136 F.T.C. 956, 970-71 (2003)—though that order was vacated by the Eleventh Circuit pursuant to that court's pre-*Actavis* precedent, *see* Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1058 (11th Cir. 2005).

36. *See Actavis*, 133 S. Ct. at 2231 ("The patent here may or may not be valid, and may or may not be infringed.").

37. *Id.* at 2236.

38. *See id.* at 2237. The Court mentioned that "traditional settlement considerations, such as avoided litigation costs or fair value for services," are acceptable justifications for a reverse payment. *See id.* at 2236. It also suggested that "[t]here may be other justifications," without identifying what those justifications are. *See id.*; *see also* 1 HOVENKAMP ET AL., *supra* note 8, § 16.01[D], at 16-22, -26 to -27 (discussing "[t]he Court's repeated references to only two justifications" that permissibly explain a large reverse payment).

The California Supreme Court took a similar approach to this issue, though it more explicitly left the door open to a finding in the future that those two traditional considerations would be the only procompetitive justifications for a reverse payment settlement agreement. *See In re* Cipro Cases I & II, 348 P.3d 845, 870 (Cal. 2015) (declining to adopt a per se prohibition on all payments "in excess of litigation costs and collateral products and services" because the court could not "say with reasonable certainty—yet—that [it had] posited every possible justification that might render a particular reverse payment settlement procompetitive").

payment is a proxy for patent strength, it will "normally not [be] necessary to litigate patent validity" to resolve the antitrust claim.[39]

2. An inherently probabilistic inquiry

By emphasizing that "the relevant anticompetitive harm" from a reverse payment is that it "prevent[s] the *risk* of competition,"[40] the *Actavis* Court accepted the view of a large body of scholarship that a patentee possesses a probabilistic right to exclude.[41] Specifically, a patent with a particular probability of being invalidated[42] can be thought of like a patent that is certainly valid for a shorter remaining life span.[43] That is, a patent that expires in ten years but that has a 50% chance of being invalidated tomorrow can be thought of, at least roughly, like a valid patent that expires in five years.[44] In this stylized example, an agreement between a brand-name company and its future generic competitor that delays generic entry for five years should likely not be condemned by the antitrust laws.[45] Without more, such an agreement looks, in expectation, like the parties to the patent litigation privately agreed on the probability that the patent would be invalidated and cut a deal that leaves the risk-neutral consumer indifferent: The settlement replaces a coin

39. *See Actavis*, 133 S. Ct. at 2236.

40. *See id.* (emphasis added).

41. *See Cipro*, 348 P.3d at 859 ("[A] critical insight undergirding *Actavis* is that patents are in a sense probabilistic, rather than ironclad: they grant their holders a potential but not certain right to exclude."); *id.* at 860 n.9 ("The *Actavis* treatment of patents as in some sense probabilistic rests on a substantial body of scholarship suggesting patents are best understood this way."); *id.* ("The Supreme Court majority's views are conclusive as to which side of this philosophical divide over the proper treatment of patents is correct, and we follow them."). For an example of this body of scholarship, see Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, J. ECON. PERSP., Spring 2005, at 75.

42. For convenience, this Note often uses "invalidity" as a shorthand reference to any reason why a patentee does not possess a valid right to exclude the competitors with whom it reaches a reverse payment agreement. When used in this way, the term also encompasses noninfringement. *Cf. Actavis*, 133 S. Ct. at 2231 (identifying anticompetitive potential in agreements that eliminate the risk that a patent will be held either invalid or not infringed).

43. *See Cipro*, 348 P.3d at 864 (explaining that if "a patent [has] a 50 percent chance of being upheld," then "[a]fter litigation, on average, consumers would be subject to a monopoly for half the remaining life of the patent").

44. *See id.* Incorporating risk aversion and discounting for the time value of money would of course enhance the precision of this framework, but the important point for this example is that a patent whose validity is uncertain can be analogized to a valid patent in much the same way as an uncertain future payoff has a certainty equivalent. *See generally Certainty Equivalent*, INVESTOPEDIA, https://perma.cc/W447-JU7K (archived Feb. 28, 2018) ("[A] certainty equivalent is a guaranteed return that someone would accept rather than taking a chance on a higher, but uncertain, return.").

45. *See* 1 HOVENKAMP ET AL., *supra* note 8, § 16.01[F].

flip between immediate entry and a ten-year monopoly with a certain five-year monopoly.

The antitrust concern here is that the parties might craft a pay-for-delay agreement ensuring that entry happens not after five years but after, say, seven years, cheating consumers out of two years (in expectation) of a competitive market. From the standpoint of the generic challenger, each moment of delay past the expected entry date—five years in this example—is a loss of potential profits for which the challenger has to be compensated.

The "*Actavis* inference" is that when we observe a settlement in which the generic manufacturer (1) agrees not to enter until some future date but (2) receives something valuable in exchange that cannot otherwise be explained, we can (3) infer pay-for-delay.[46] This is so because the patent's "expected life had enforcement been sought"[47]—an entry date a risk-neutral consumer would be willing to accept—is sooner than whatever date, if any, the generic manufacturer negotiated. In the Court's words, the "large and unjustified" payment from the brand-name firm to the generic manufacturer "likely seeks to prevent the risk of competition."[48] Crucially, the reason "it is normally not necessary to litigate patent validity to answer the antitrust question" is that the inference at the core of the decision is a way *around* litigating patent validity.[49] The Court's use of the qualifier "normally"—which some commentators and courts fixate on as a way of suggesting that there are vast swaths of carve-outs from *Actavis* where patent validity *does* need to be litigated, as discussed further in Parts II and III below—merely recognizes that there may be scenarios where the inference is not the path to establishing a patent-related antitrust violation. Perhaps the only examples the Court had in mind were patent-related antitrust claims that are not specific to reverse payments, like "sham" patent litigation claims.[50]

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46. *See* Edlin et al., *supra* note 26, at 589 (capitalization altered).

47. *See Cipro*, 845 P.3d at 864.

48. *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2236-37 (2013).

49. *See id.*

50. Context suggests that this may indeed be what the Court meant. *See id.* at 2236 ("The ['scope of the patent' rule] does avoid the need to litigate the patent's validity (and also, any question of infringement). But to do so, it throws the baby out with the bath water, and there is no need to take that drastic step. That is because it is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham)." (citation omitted)). Antitrust plaintiffs prove a "sham" patent litigation claim by showing that a patentee "knew or should have known at the time it filed [an infringement] lawsuit or took other exclusionary action that the IP right being asserted was invalid or unenforceable in the particular situation." *See* 3 AREEDA-HOVENKAMP, *supra* note 3, ¶ 706a, at 262 (4th ed. 2015).

The Court also noted an important corollary proposition that necessarily follows from viewing the anticompetitive harm here as a delay in the expected entry date: The inference applies even where there is "a small risk of invalidity."[51] Consider what it would mean to toss out antitrust claims only because the risk of invalidity is below some threshold—say, 50%, as some courts appear to effectively be doing in private antitrust cases after *Actavis*.[52] Under that rule, a small change in the facts underlying the above hypothetical agreement would be dispositive: If the probability of invalidating the patent with ten years of remaining life were 40%, even an agreement that delays entry by four years in expectation—from six years to ten, likely causing *more* anticompetitive harm than the illegal agreement to delay entry from five years to seven described above—would survive antitrust scrutiny. That result cannot be harmonized with the logic of the expected entry date approach endorsed in *Actavis*, something courts adopting the approach criticized in this Note fail to acknowledge.

3. Rejection of the "scope of the patent" test's black-and-white inquiry

Before *Actavis*, some federal courts of appeals had crafted a very different solution—the "scope of the patent" test—to resolve antitrust challenges to reverse payment settlement agreements.[53] These courts reasoned that the antitrust claim cannot proceed in the face of uncertainty about the validity of the patent. Instead of treating the patent probabilistically, these courts invoked the presumption of patent validity[54]—which of course the antitrust plaintiff would not be able to rebut without getting into the merits of the patent case that has already settled. Once the patent is assumed valid, an antitrust plaintiff attacking a reverse payment settlement has no claim: It is within the "scope of the patent" to exclude competitors until any date at or before the patent's expiration, so no harm to competition can result from an agreement that merely recognizes as much.[55] Indeed, under this approach, the seven-year wait

51. *See Actavis*, 133 S. Ct. at 2236; *see also Cipro*, 845 P.3d at 863 (citing *Actavis* in support of the proposition that an agreement can be anticompetitive "even when the patent is likely valid").

52. *See infra* notes 100-01 and accompanying text.

53. *See* Petition for a Writ of Certiorari at 12, *Actavis*, 133 S. Ct. 2223 (No. 12-416), 2012 WL 4750283 (explaining that "the so-called scope-of-the-patent" approach had been adopted by three courts of appeals).

54. *See* FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1308 (11th Cir. 2012) (citing 35 U.S.C. § 282), *rev'd and remanded sub nom. Actavis*, 133 S. Ct. 2223. The presumption of validity is rebuttable in a patent suit. *See* Microsoft Corp. v. i4i Ltd. P'ship, 564 U.S. 91, 95 (2011).

55. *See Watson*, 677 F.3d at 1312 ("[A]bsent 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.").

for generic competition in the stylized example above—which, by hypothesis, is in expectation a two-year delay from the date risk-neutral consumers would accept—looks like a boon to consumers: The face value of the patent says that it can exclude competition for ten years, so entry in seven years looks like a three-year advance.

In addition to granting the settling companies a presumption of patent validity, the "scope of the patent" test banned an antitrust plaintiff from taking the next logical step of proving, as part of its claim, that the patent was in fact invalid. Such a "turducken task" (an adjudication of patent validity inside an antitrust lawsuit) would be too unwieldy, according to these courts.[56] Leaving the antitrust plaintiff no way to prove pay-for-delay, then, these courts dismissed antitrust attacks on reverse payment settlement agreements if patent validity remained unresolved.[57]

By holding that patent validity need not always be litigated to show that a reverse payment settlement violated antitrust law, the *Actavis* Court squarely rejected the "scope of the patent" test. Dissenting from this decision, Chief Justice Roberts (joined by Justices Scalia and Thomas) would have adopted that test.[58] The dissent confirms how central the treatment of uncertainty about patent validity is to the divergence in approaches. Unlike the majority, the dissent found the reasoning that "a patent holder violates the antitrust laws merely because the settlement took away some chance that his patent would be declared invalid by a court" to be "flawed."[59] Among other things, the dissent insisted that "a patent is either valid or invalid."[60] As discussed above, the majority rejected such a black-and-white approach, instead adopting what the California Supreme Court described as a "treatment of patents as in some sense probabilistic."[61]

56. *See, e.g., id.* at 1315. *Merriam-Webster* defines a "turducken" as "a boneless chicken stuffed into a boneless duck stuffed into a boneless turkey." *Turducken*, MERRIAM-WEBSTER, https://perma.cc/4X9Z-55GB (archived Feb. 24, 2018). The Eleventh Circuit was perhaps more properly concerned about two-thirds of a turducken task, as these cases involve only one claim (the patent "chicken") stuffed into another (the antitrust "duck"). Regardless of the appropriate culinary analogy, note that the *Actavis* Court's approach also avoids the "turducken task" because the inference of anticompetitive effects follows without the need to litigate patent validity. *See supra* text accompanying note 49.

57. *See, e.g.*, *Watson*, 677 F.3d at 1306, 1315 (affirming dismissal under Rule 12(b)(6) of the Federal Rules of Civil Procedure).

58. *See Actavis*, 133 S. Ct. at 2238, 2244 (Roberts, C.J., dissenting) ("[S]ettling a patent claim *cannot possibly* impose unlawful anticompetitive harm if the patent holder is acting within the scope of a valid patent and therefore permitted to do precisely what the antitrust suit claims is unlawful.").

59. *Id.* at 2244.

60. *See id.*

61. *See In re* Cipro Cases I & II, 348 P.3d 845, 860 n.9 (Cal. 2015).

B. The Causation Requirement for Private Plaintiffs

Unlike *Actavis*, which was a government enforcement action brought by the FTC, many of the cases in which courts have since assessed whether a reverse payment settlement agreement violates the antitrust laws have been brought by private parties.[62] And unlike the government, which "enjoys automatic standing" to secure a decision in its favor whenever there is an antitrust violation,[63] private plaintiffs must establish "antitrust standing" to prevail.[64]

Because the standing inquiry is irrelevant in a government enforcement case, *Actavis* itself is, naturally, silent on what that inquiry should look like. Importantly, however, "nothing in [*Actavis*]'s discussion of the legal rules at the boundary between antitrust and patent law hinged on the happenstance that the case under review involved a public prosecutor."[65] Had the Court intended to limit its reasoning to public enforcement cases, it would have made sense for the Court to signal this in some way—particularly when presented with the argument that a holding in favor of the FTC would bring about undesirable effects in private reverse payment lawsuits, which "far outnumber those brought by the FTC."[66]

As a result of the *Actavis* Court's silence on antitrust standing, courts and commentators have since taken up the task of filling in that inquiry in private enforcement cases. While there is occasionally imprecision in the labels invoked,[67] the heart of the controversy surrounds one particular standing requirement: that a private plaintiff show causation of injury-in-fact. This inquiry—which for the purposes of this Note can be considered a single

62. *See, e.g.*, *infra* Part II (discussing cases brought by private parties).

63. *See* 2A AREEDA-HOVENKAMP, *supra* note 3, ¶ 335f, at 90 (4th ed. 2014).

64. *See id.* ¶ 335a, at 76-77 (capitalization altered). A private plaintiff in federal court would of course also need to show Article III standing. But because antitrust standing "requires more than the constitutional minimum for the 'case or controversy' that brings jurisdiction to Article III courts," *id.* at 77, distinct analysis of Article III standing is superfluous.

65. *Cipro*, 348 P.3d at 858-59.

66. *See* Brief for Respondent Solvay Pharmaceuticals, Inc., *supra* note 4, at 40.

67. *See, e.g.*, Am. Sales Co. v. AstraZeneca LP (*In re* Nexium (Esomeprazole) Antitrust Litig.), 842 F.3d 34, 59-60 (1st Cir. 2016) (indicating that a question on a special jury verdict form about what would have happened in the absence of the settlement agreement—that is, a question about causation—serves the purpose of establishing "whether these private plaintiffs have suffered an 'injury of the type the antitrust laws were intended to prevent'" (quoting Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977))); *cf.* 2A AREEDA-HOVENKAMP, *supra* note 3, ¶ 335e, at 88 (4th ed. 2014) (lamenting that "courts frequently speak with much less clarity" than the treatise would prefer when those courts distinguish between the various requirements for antitrust standing).

requirement referred to more simply as "causation"—requires plaintiffs to show that but for the antitrust violation they attack, there would have been more competition and that the absence of that competition injured them.[68] A plaintiff attacking a typical pharmaceutical reverse payment settlement agreement therefore must establish that the challenged agreement actually delayed generic entry. Once it has done so, there is little reason to suspect that the remaining standing requirements pose any categorical concern.[69]

Because it is a component of the standing inquiry, the causation requirement imposes a burden distinct from what a plaintiff must prove to establish an antitrust violation.[70] Though perhaps obvious upon reflection, insufficiently rigorous attention to this point has led at least two district courts since *Actavis* to erroneously conflate aspects of the violation and standing inquiries in reverse payment settlement cases.[71] Requiring more from a private plaintiff

68. *See* 2A AREEDA-HOVENKAMP, *supra* note 3, ¶ 338, at 117.

69. The Areeda-Hovenkamp treatise identifies four additional standing requirements: (1) injury to business or property; (2) antitrust injury; (3) plaintiffs who are not remote, derivative, duplicative, or inferior; and (4) reasonably ascertainable damages. *See id.* ¶¶ 336-37, 339-40. Applying each requirement in turn to a reverse payment challenge demonstrates why none poses a special challenge here.

First, the "'business or property' requirement is virtually always satisfied provided there is some kind of injury that can properly be characterized as economic." *Id.* ¶ 336, at 97. In a reverse payment case, overpayment for the settling companies' products surely meets this requirement.

Second, antitrust injury is lacking when "an assumed proximately caused injury-in-fact" is not "the kind that antitrust law is designed to prevent." *See id.* ¶ 335e, at 88. This requirement bars recovery for "injuries resulting from competition," *id.* ¶ 337a, at 104, such as when a competitor complains that its rivals have injured it by "depriving [it] of the benefits of increased [market] concentration," *Brunswick*, 429 U.S. at 488—that is, depriving it of the ability to gain from the very anticompetitive harm antitrust law is designed to prevent. This too is not an issue for a reverse payment plaintiff, which is typically a drug purchaser claiming that it has been overcharged—not a competitor complaining that prices are too low.

Third, the "proximity" requirement bars plaintiffs whose injuries are too attenuated, ensuring, among other things, that the defendant does not pay double recovery for the same injury. *See* 2A AREEDA-HOVENKAMP, *supra* note 3, ¶ 339a, at 130 (4th ed. 2014). There is no reason to suspect that a reverse payment settlement case presents any special challenges here that would be absent from, for example, a claim by similar plaintiffs that pharmaceutical company defendants had engaged in illegal price fixing.

Fourth, the reasonably ascertainable damages requirement ensures that a liability theory premised on "damages that do not exist" cannot move forward. *See id.* ¶ 340, at 147-48, 179. Because a successful plaintiff in a reverse payment case will have proved delay beyond an expected entry date, reasonable methods exist for calculating damages. *See infra* note 76.

70. *See* 2A AREEDA-HOVENKAMP, *supra* note 3, ¶ 335e, at 88 (4th ed. 2014) ("[W]e try *never* to confuse the standing inquiry with doubts about the substantive merits.").

71. *See* Brief of Federal Trade Commission as Amicus Curiae in Support of No Party at 19-21, *In re* Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132 (3d Cir.

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but framing it as part of the violation inquiry hampers courts' ability to correctly assess whether there has been an antitrust violation in the first place. This point has not been lost on the FTC, which has filed amicus briefs urging appellate courts to correct district courts' erroneous conflation of an antitrust violation with questions of antitrust standing.[72] The essence of the FTC's concern is that when courts import questions of standing into their analysis of the violation itself and then hold that there was no violation, they incorrectly heighten the showing that will be required of government enforcers in future cases.[73]

It might be tempting to write off this conflation concern in private cases as a mere difference in the heading under which the causation analysis falls. But that would be a mistake. For starters, infecting the violation inquiry with causation questions that have no place there breeds doctrinal confusion about what the violation prong requires. Moreover, courts that have conflated the two inquiries have not simply picked up the right causation analysis and moved it over into the wrong doctrinal box; they have gotten the analysis itself wrong, too.[74] It is therefore crucial that courts take the preliminary step of cabining their causation analysis: "To test standing," courts "should assume the existence of a violation."[75]

Before proceeding, a preliminary explanation of two features of this Note's scope is warranted. First, the causation analysis proposed here explains why plaintiffs should not face a categorical hurdle that all but requires entry of judgment for the defense on the question of liability. Issues that arise only in the calculation of damages are beyond this Note's scope.[76] Second, the examples

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2017) (Nos. 15-3559 et al.), 2016 WL 1040063 [hereinafter FTC *Wellbutrin* Brief] (arguing that the district court in *Wellbutrin* "incorrectly characterized the nature and source of the distinction" between the burden faced by the FTC and that faced by private parties); Brief of Amicus Curiae Federal Trade Commission in Support of No Party at 2, 8-12, 20-23, Am. Sales Co. v. AstraZeneca LP (*In re* Nexium (Esomeprazole) Antitrust Litig.), 842 F.3d 34 (1st Cir. 2016) (Nos. 15-2005 et al.), 2016 WL 1009287 [hereinafter FTC *Nexium* Brief] (explaining the distinction between the violation and standing inquiries and discussing errors in the district court's reasoning with respect to that distinction); *see also Nexium*, 842 F.3d at 59 (acknowledging that "conflation of antitrust violation and antitrust injury" had "crept into the district court's post-trial opinion").

72. *See* FTC *Wellbutrin* Brief, *supra* note 71, at 19-21; FTC *Nexium* Brief, *supra* note 71, at 8-12, 20-23.

73. *See* FTC *Wellbutrin* Brief, *supra* note 71, at 19; FTC *Nexium* Brief, *supra* note 71, at 21.

74. *See infra* Part III.

75. 2A AREEDA-HOVENKAMP, *supra* note 3, ¶ 335f, at 91 (4th ed. 2014).

76. It is worth briefly noting that there is no reason to believe that private plaintiffs will be doomed when the time comes to calculate damages. Whereas the relevant question for causation is *whether* the agreement delayed generic entry, a damages assessment will require measuring *how much* entry was delayed. *See* Edlin et al., *supra* note 26, at 602 ("[C]alculating value is likely to require establishing a but-for entry date, or estimate of

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discussed in this Note all concern reverse payment agreements struck in the context of a particular set of pharmaceutical regulations. While this Note's analysis is not expressly limited to that category of agreements—just as the *Actavis* Court's holding was not limited in this way[77]—there are good reasons to think that almost all reverse payment agreements occur in the pharmaceutical industry.[78]

II. An Emerging Split in Approaches to Private Plaintiff Recovery

As described above, the main challenges unique to liability in a reverse payment settlement antitrust claim brought by a private plaintiff have to do with causation. To prevail, a private plaintiff must show that but for the reverse payment settlement agreement, generic entry would have happened earlier.[79]

One group of courts, backed by some commentators, has required plaintiffs to prove precisely how generic entry would have occurred earlier in the absence of the agreement. This group's approach creates two major barriers to recovery for private plaintiffs: Both uncertainty about patent validity and insufficient evidence about alternative settlement agreement prospects can be death knells for a private suit. Another approach sees no substantial problem with either of these barriers, reasoning instead that an antitrust violation here

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the date on which generic entry would have occurred had the pay-for-delay settlement not intervened."). Such a damages assessment is an achievable task. The Areeda-Hovenkamp treatise suggests that "in the absence of factors strongly suggesting a different date, entry would be presumed to have occurred on the expected entry date under litigation, or alternatively, the date of the settlement itself." AREEDA-HOVENKAMP, *supra* note 3, ¶ 345a, at 68 (Supp. 2016) (footnote omitted). There are several possibilities for estimating the expected entry date under litigation, including "pro rata reduction in the patent term based on the probability that the patent in question will be found invalid or uninfringed." *See id.* at 68 n.5.

77. *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013) (discussing without qualification "the risk of significant anticompetitive effects" from a large and unjustified reverse payment).

78. *See supra* note 13; *see also Actavis*, 133 S. Ct. at 2235 ("[S]cholars in the field tell us that 'where only one party owns a patent, it is virtually unheard of outside of pharmaceuticals for that party to pay an accused infringer to settle the lawsuit.'" (quoting 1 HOVENKAMP ET AL., *supra* note 8, § 15.3 n.161 (2d ed. Supp. 2011))).

79. The plaintiff must also be someone who would have benefited from more competitive pricing of the particular drug at issue—otherwise, some other person may have been injured, but the wrong plaintiff has sued. *See* 2A AREEDA-HOVENKAMP, *supra* note 3, ¶ 345, at 179 (4th ed. 2014) ("Of course, a consumer cannot obtain damages without showing that she actually paid more or received less than she would have in the absence of the violation."). Because that analysis does not turn on the fact that the underlying claim is about a reverse payment settlement agreement, it is not treated here as a separate hurdle.

means generic entry has been delayed beyond the patent's "expected life had enforcement been sought."[80]

A. A Narrow Approach

Under one approach to causation, plaintiffs must prove precisely *how*, absent the illegal settlement agreement, generic entry would have happened earlier. There are three basic stories plaintiffs faced with such a requirement can tell. They can argue that absent the settlement, (1) the parties to the patent dispute would have litigated to a judgment of invalidity or noninfringement, allowing the generic challenger to enter earlier; (2) the generic challengers, confident they would ultimately prevail in their patent suit, would have entered the market "at risk" while the patent suit remained ongoing; or (3) the parties to the patent dispute would have reached a different settlement containing an earlier generic entry date but no illegal reverse payment.[81]

The logical starting point from which this approach stems is the requirement it imposes that plaintiffs pick among the possible paths to generic entry and then prove specifically how entry would have occurred in the absence of the illegal settlement agreement. (Note that existing commentary focuses not on this starting point but instead on the importance of proof of patent validity;[82] as discussed below, this is one important piece of the approach but does not account for another part.) Thus, the telltale sign that a court has adopted this approach is that it will outline possible causation paths and assess whether the plaintiff has produced enough to succeed on any single theory.

Three courts have taken this approach: the Third Circuit in *Wellbutrin*,[83] the First Circuit in *Nexium*,[84] and Judge Goldberg of the Eastern District of Pennsylvania in *Apotex*.[85] As discussed below, this approach differs sharply from the course laid out by other courts; those courts say nothing about proof of the specific causation path, reasoning instead that the simultaneous foreclosure of all these possible paths to earlier generic entry can be enough to cause delayed entry *in expectation*.[86]

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80. *See In re* Cipro Cases I & II, 348 P.3d 845, 853, 864 (Cal. 2015).

81. *See In re* Opana ER Antitrust Litig., 162 F. Supp. 3d 704, 720 (N.D. Ill. 2016).

82. *See* Simmons et al., *supra* note 21, at 26 (focusing only on the patent validity issue discussed in Part II.A.1 below); Thomas et al., *supra* note 25 (same).

83. *See In re* Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 163-70 (3d Cir. 2017).

84. *See* Am. Sales Co. v. AstraZeneca LP (*In re* Nexium (Esomeprazole) Antitrust Litig.), 842 F.3d 34, 59-65 (1st Cir. 2016).

85. *See* Apotex, Inc. v. Cephalon, Inc., 255 F. Supp. 3d 604, 612-14 (E.D. Pa. 2017).

86. *See infra* Part II.B.

Courts that require plaintiffs to prove one of these causation paths have imposed two burdens that are absent from the alternative approach. First, they require a plaintiff proceeding on either a litigation-to-invalidity or an at-risk launch theory to produce evidence that the patent underlying the dispute was invalid or not infringed. Second, they require a plaintiff proceeding on a zero-payment alternative settlement theory to produce evidence that such a settlement would have actually occurred.

1. Uncertainty about patent validity can be fatal to private plaintiffs proceeding on at-risk launch or litigation-to-invalidity theories

In the Third Circuit's *Wellbutrin* case, the panel affirmed the district court's grant of summary judgment, explaining that the plaintiffs could only succeed on their at-risk launch theory if they could "show that the launch would have been legal."[87] The court explained that the plaintiffs could not do so because an earlier generic launch was "effectively blocked by federal patent law."[88] In light of settled precedent holding that "no antitrust standing exists when a plaintiff's grievance is caused by a regulatory scheme rather than by the defendant's actions," the panel concluded that the only way plaintiffs could prevail would be to make a "factual" showing that "but for the challenged agreements, [the generic manufacturer] *would have been able* to launch its [competing product] without running afoul of [the disputed] patent."[89] This "factual" analysis was

87. *See Wellbutrin*, 868 F.3d at 142-43, 165. The *Wellbutrin* plaintiffs primarily relied on an at-risk launch theory because, unlike in many other reverse payment cases, the challenged settlement allowed an appeal of part of the underlying patent litigation to continue. *See id.* at 162 n.50.

88. *See id.* at 165.

89. *See id.* at 166 (emphasis added). To be sure, the court framed the need for this showing as a byproduct of the way the plaintiffs had argued this particular case, not a general requirement across cases. *See id.* But that framing obfuscates the court's conclusion that such a showing was necessary in the first place. For starters, the court could have agreed with the plaintiffs' primary argument that it is wrong to "treat[] a patent as self-enforcing, as did the 'scope of the patent test' rejected by *Actavis*," *see* Plaintiffs-Appellants'/Cross-Appellees' Submission of Redacted First- and Third-Step Briefs ex. A at 83, *Wellbutrin*, 868 F.3d 132 (Nos. 15-3559 et al.). And even after determining that it was necessary to inquire into patent merits, the court could have held that plaintiffs need only produce *some* proof of patent weakness. *Cf.* United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA (*Lidoderm*), No. 14-md-02521-WHO, 2017 WL 5068533, at *4-5 (N.D. Cal. Nov. 3, 2017) (rejecting a requirement that plaintiffs prove that the generic manufacturer *would have* won the patent dispute in favor of a requirement that they prove that the generic manufacturer *could have* won). Instead, the *Wellbutrin* court extracted from the plaintiffs' backup argument that the generic manufacturer's success in the patent litigation was "likely," *see* Plaintiffs-Appellants'/Cross-Appellees' Submission of Redacted First- and Third-Step Briefs, *supra*, ex. A at 85, a requirement that the generic manufacturer's success be *more likely than not*, *see Wellbutrin*, 868 F.3d at 166.

fatal to the *Wellbutrin* plaintiffs at the summary judgment stage: According to the Third Circuit, neither the reverse payment itself (as a proxy for patent weakness) nor an expert opinion about the likely outcome of continued litigation would allow a reasonable jury to conclude that the generic manufacturer would have prevailed in the patent litigation.[90]

Following a similar approach, the First Circuit held in *Nexium* that a plaintiff's ability to prove causation through either litigation-to-invalidity or at-risk launch theories depends on whether the relevant patents "were invalid or not infringed by a generic version."[91] When there is "no adequate evidence that any of [the relevant] patents would be adjudicated invalid," judgment must be entered for the defendants.[92] This is so because of the "likelihood that [the relevant] patents, not [the] reverse payment . . . , were the bar to a generic launch."[93] In light of the lack of evidence of invalidity or noninfringement in *Nexium*, the First Circuit found no error in the district court's decision to reject these two causation theories at the summary judgment stage.[94] Nor was the district court wrong to subsequently reason, in granting judgment as a matter of law on several issues following the plaintiffs' presentation of their case in chief to the jury, that the plaintiffs could not succeed on "any theory involving the invalidity" of the relevant patents.[95] These were among the several bases on which the panel affirmed the result from the first—and so far only—post-*Actavis* trial regarding a reverse payment settlement claim that proceeded to a jury verdict.[96]

90. *See Wellbutrin*, 868 F.3d at 167-70. These two arguments (payment as a proxy and an expert opinion on the likely outcome of the patent challenge) were analyzed as part of a "litigation-based scenario." *See id.* The court also found that the plaintiffs could not succeed under a "license-based scenario" because they could not show that but for the settlement, the generic manufacturer would have obtained a license to the relevant patent. *See id.* at 166-67. The court's analysis of the "license-based scenario" was similar to its approach to the "litigation-based scenario": The court searched for proof that the generic manufacturer would have obtained a license to the patent, concluding that this causal mechanism failed because no reasonable jury could infer from the evidence presented that such an agreement would have been reached. *See id.*

91. *See* Am. Sales Co. v. AstraZeneca LP (*In re* Nexium (Esomeprazole) Antitrust Litig.), 842 F.3d 34, 62 (1st Cir. 2016); *see also Wellbutrin*, 868 F.3d at 165 (citing *Nexium* favorably).

92. *See Nexium*, 842 F.3d at 62 (quoting the district court's opinion).

93. *See id.* at 63.

94. *See id.* at 62.

95. *See id.* at 49, 62.

96. *See id.* at 65; *see also id.* at 39 (referring to the trial as "the first pharmaceutical-settlement antitrust action tried before a jury since the Supreme Court's decision" in *Actavis*); Rachel Graf, *Apotex, Ranbaxy End Pay-for-Delay Suit over Narcolepsy Med*, LAW360 (July 7, 2017, 5:49 PM EDT), https://perma.cc/HLJ5-WSDU (reporting that a midtrial settlement ended the "second" such jury trial).

This approach has also been endorsed by Judge Goldberg of the Eastern District of Pennsylvania, who presided over the *Apotex* trial that ended with a midtrial settlement.[97] The approach advocated by two sets of commentators is also similar. In a piece published before any of these courts had weighed in, Ian Simmons and colleagues reasoned that "some form of patent analysis and litigation is necessary in private actions post-*Actavis* if the defense asserts that it was the branded company's patents that foreclosed the generic company's market entry."[98] More recently, Peter Thomas and colleagues surveyed several of the court decisions discussed in this Note and concluded that the causation "inquiry requires an investigation into whether the patent would have survived the challenge."[99]

Three issues embedded in this approach warrant further attention. First, neither the First nor the Third Circuit has made clear precisely how much proof the plaintiff must produce that the generic challenger would have successfully shown that the patent was invalid or not infringed. But both hint—the Third Circuit far more clearly—that what they are looking for is evidence that the probability the underlying patent was invalid or not infringed is at least 50%.[100] One of the commentaries whose approach aligns

97. *See* Apotex, Inc. v. Cephalon, Inc., 255 F. Supp. 3d 604, 614 (E.D. Pa. 2017) (finding that "[t]he clear import of *Nexium* and [the district court's decision the Third Circuit ultimately affirmed in] *Wellbutrin* is that a plaintiff must offer some evidence of non-infringement or patent invalidity in order to proceed on an at-risk launch theory of causation" and reasoning on this basis that a court judgment on the validity of the underlying patent was "highly probative" to the plaintiffs' case for causation); *see also* Graf, *supra* note 96 (reporting the midtrial settlement).

98. Simmons et al., *supra* note 21, at 26.

99. *See* Thomas et al., *supra* note 25.

100. *See In re* Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 169 (3d Cir. 2017) (relying on an expert's analysis that the generic manufacturer "would only have a 20% chance of winning" the patent suit to support its conclusion that there was insufficient evidence to survive summary judgment); *id.* at 166 (requiring proof that "but for the challenged agreements, [the generic manufacturer] *would have been able* to launch its [competing product] without running afoul of [the disputed] patent" (emphasis added)); *Nexium*, 842 F.3d at 63 ("The district court . . . did not err by requiring some evidence of the patents' invalidity or noninfringement before allowing the plaintiffs to pursue an at-risk launch theory."). The First Circuit's rule is markedly less clear than the Third Circuit's because of its focus on the line between no proof and some proof. Whether this imposes a 50% threshold may be an open question in that circuit, particularly in light of the panel's subsequent clarification that "[a]ll the panel's holding did was recognize that, given the peculiarities of this case, the district court in no way forced a 'detailed exploration' of patent validity within an antitrust case." *See* Am. Sales Co. v. AstraZeneca LP (*In re* Nexium (Esomeprazole) Antitrust Litig.), 845 F.3d 470, 475 (1st Cir. 2017) (quoting FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013)) (denying rehearing); *see also* United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA (*Lidoderm*), No. 14-md-02521-WHO, 2017 WL 5068533, at *4 (N.D. Cal. Nov. 3, 2017) ("'Some evidence' is not the same as requiring plaintiffs to prove

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with these courts' explicitly advocates a 50% threshold.[101]

Second, this approach leaves unanswered important follow-on questions about what the patent validity litigation will look like. Recall that under the "scope of the patent" test, plaintiffs were not permitted to attempt the "turducken task" of litigating patent validity within an antitrust suit.[102] Under the narrow approach to causation, courts are again demanding proof of how the underlying patent dispute would have turned out—without acknowledging, as the "scope of the patent" test did, that it may be prudent to stop plaintiffs from going too far down the patent validity rabbit hole. However courts may expect plaintiffs to respond to their demands for this proof, the mere indication that the inquiry is necessary may ultimately prove fatal in practice to private plaintiffs, who would likely be reticent to pursue the "turducken" strategy even if there were some mechanism available for them to do so. Patent infringement cases bear notoriously high litigation costs,[103] and antitrust plaintiffs apparently risk losing their cases on causation grounds if the best they can come up with at the end of the day is proof of "a small risk of invalidity"—even though that proof could be enough to establish an antitrust violation under *Actavis*.[104] A private plaintiff who does not have ready-made proof of invalidity (such as a final judgment of invalidity like the one available in *Apotex*[105]) may therefore, as a practical matter, lose on its at-risk launch or litigation-to-invalidity theory as soon as the court adopts this approach.

Third, by emphasizing the need to prove patent invalidity or noninfringement in certain cases, this approach results in a categorical distinction between the ability of the government to prevail without proving patent validity and the ability of private plaintiffs to prevail using a similar degree of

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that the generic defendant *would have* won, only that it *could have*." (quoting *Nexium*, 842 F.3d at 63)).

101. *See* Thomas et al., *supra* note 25 ("This article argues that private plaintiffs seeking monetary damages must allege, and eventually prove *by a preponderance of the evidence*, patent invalidity or non-infringement in order to succeed on a claim for damages under [*Actavis*]." (emphasis added)).

102. *See supra* note 56 and accompanying text.

103. *See* AM. INTELLECTUAL PROP. LAW. ASSOC., REPORT OF THE ECONOMIC SURVEY 2015, at 37 (2015), https://perma.cc/2K95-MSTD (estimating the cost of the type of suit at issue here to be in the millions of dollars).

104. *See Actavis*, 133 S. Ct. at 2236; *see also supra* notes 51-52 and accompanying text (discussing the close nexus between *Actavis*'s holding and its application to cases involving a small risk of invalidity).

105. *See* Apotex, Inc. v. Cephalon, Inc., 255 F. Supp. 3d 604, 607 (E.D. Pa. 2017) (indicating that the case presented the question how to structure a reverse payment antitrust lawsuit when "the relevant patent is found to be invalid and not infringed several years after the reverse-payment settlement agreements were executed"); *id.* at 609 (describing the procedural history through which the final judgment of invalidity was rendered).

proof. Recall that under *Actavis*, anticompetitive delay can be inferred from a large, unjustified reverse payment, in part because that payment demonstrates uncertainty about patent validity.[106] A commentary by Simmons and colleagues has rejected the notion that this means delay has in fact been caused by the payment, arguing that the *Actavis* "shortcut" of using a large and unjustified payment as a "proxy for patent coverage" simply "should not apply in private actions."[107] The inference upon which the *Actavis* Court relied in order to reject the "scope of the patent" test is, under this view, a tool whose use in a private action would require "end-run reasoning" around causation that "does violence to the Clayton Act."[108] Simmons and colleagues have thus laid bare what courts adopting this approach are doing: creating a categorical distinction between cases brought by the government and those brought by private plaintiffs.

Yet courts adopting this approach have obscured the fact that they are drawing such a distinction between public and private enforcement. In a baffling footnote, the *Wellbutrin* court instead framed the *Actavis* Court's guidance that "it is normally not necessary to litigate patent validity" as a prediction about how these cases should proceed in general, whether the plaintiff is public or private; the panel went on to explain that "[t]he present case appears to vindicate the Chief Justice's" argument—in dissent—that patent validity normally needs to be litigated.[109] It is unsurprising that the panel grasped for some way to explain away this language from *Actavis*; perhaps its willingness to reach inexplicably into the dissent for a reason to do so owed to its reluctance to adopt the textual justification for a public/private distinction the district court below had relied on, which the FTC had rebuked in its amicus brief.[110]

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106. *See supra* text accompanying notes 46-48.

107. *See* Simmons et al., *supra* note 21, at 26.

108. *See id.*

109. *See In re* Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 167 n.58 (3d Cir. 2017) (quoting *Actavis*, 133 S. Ct. at 2236).

110. The district court had explained that while it may be the case that patent validity need not be litigated in "actions brought under the [Federal Trade Commission Act (FTC Act)] . . . , the Clayton Act does demand such an analysis." *In re* Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d 734, 764 (E.D. Pa. 2015), *aff'd*, 868 F.3d 132 (3d Cir. 2017); *see also* Clayton Antitrust Act of 1914, Pub. L. No. 63-212, 38 Stat. 730 (codified as amended in scattered sections of 15 and 29 U.S.C.); Federal Trade Commission Act, Pub. L. No. 63-203, 38 Stat. 717 (1914) (codified as amended at 15 U.S.C. §§ 41-58 (2016)). The court justified this conclusion by reading the FTC Act to impose a lower burden for an antitrust violation in the first place: Under section 5(n) of the Act, "the FTC must establish only that the defendant's action is '*likely* to cause injury.'" *Wellbutrin*, 133 F. Supp. 3d at 764 (quoting 15 U.S.C. § 45(n)); *see also* 15 U.S.C. § 45(n) (requiring that the FTC establish that the practice "causes or is likely to cause substantial injury to consumers"). Observing that "[t]he Supreme Court's language in *Actavis* directly tracks
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The First Circuit's *Nexium* decision employed a different solution to this roadblock: The relevant language from *Actavis* was simply not mentioned at all in that panel's original precedential decision.[111] The panel ultimately acknowledged this language in its subsequent explanation for denying rehearing, providing the cryptic response that its decision had merely "recognize[d] that, given the peculiarities of this case, the district court in no way forced a 'detailed exploration' of patent validity within an antitrust case."[112] But factual nuance aside, the *Nexium* panel's approach makes clear that plaintiffs who cannot produce sufficient proof (distinct from the inference drawn from the reverse payment) about patent validity are bound to fail as a matter of law.[113] As explained below, this contradicts the meaning of the *Actavis* Court's guidance just as squarely as the Third Circuit's approach does.[114]

2. Plaintiffs proceeding on a zero-payment alternative settlement theory must produce evidence that such a settlement would have actually occurred

As discussed above, the third causation path available to private plaintiffs is to show that absent the illegal agreement, the parties to the patent dispute would have agreed to a settlement with an earlier generic entry date instead of the reverse payment. Both the *Nexium* and *Wellbutrin* district courts found that the plaintiffs had come up short on proof of this causal theory, resulting in judgment for the defendants that was subsequently affirmed by the courts of appeals.

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the FTC Act's 'likely to' causation standard," the district court reasoned that inferring delay without information about patent validity is limited to FTC enforcement actions. *See id.* As the FTC explained in its Third Circuit amicus brief, this reasoning is flawed: Section 5(n) of the FTC Act "is irrelevant to an FTC case brought under *Actavis*" because that section does not govern the FTC's authority over "unfair methods of competition." *See* FTC *Wellbutrin* Brief, *supra* note 71, at 21.

The flaw in the argument from section 5(n) was overlooked not only by the *Wellbutrin* district court but also by the *Nexium* district court and by the Simmons et al. and Thomas et al. pieces, all of which provided similar explanations for creating a public/private distinction with respect to the relevance of patent validity. *See In re* Nexium (Esomeprazole) Antitrust Litig., 309 F.R.D. 107, 141 (D. Mass. 2015), *aff'd*, 842 F.3d 34 (1st Cir. 2016); Simmons et al., *supra* note 21, at 24-26; Thomas et al., *supra* note 25.

111. *See* Am. Sales Co. v. AstraZeneca LP (*In re* Nexium (Esomeprazole) Antitrust Litig.), 842 F.3d 34 (1st Cir. 2016).

112. *See* Am. Sales Co. v. AstraZeneca LP (*In re* Nexium (Esomeprazole) Antitrust Litig.), 845 F.3d 470, 475 (1st Cir. 2017) (quoting *Actavis*, 133 S. Ct. at 2237).

113. *See supra* text accompanying notes 91-96.

114. *See infra* notes 180-83 and accompanying text.

In the *Nexium* trial in the District of Massachusetts, Judge Young ordered judgment for the defendants in accordance with the jury's responses to a special verdict form.[115] Despite finding that the relevant patent settlement agreement was "unreasonably anticompetitive," the jury answered "no" to the following question: "Had it not been for the unreasonably anticompetitive settlement, would [brand-name pharmaceutical company] have agreed with [generic potential competitor] that [competitor] might launch a generic version of Nexium before" the date the companies agreed to in the challenged settlement?[116] The judge instructed the jury to "suppose [the companies] were settling straight up without any anticompetitive effects" and then assess whether "that settlement license entry date [would] have been earlier than the date they agreed to."[117]

The First Circuit pointed to the causation requirement as the basis for requiring plaintiffs to produce specific factual proof to support an affirmative answer to this question.[118] The court concluded that there was sufficient evidence to allow the jury to come out either way on the question whether the parties would have agreed to an earlier entry date; in so doing, however, it pointed to strong evidence that the parties' subjective intent was not to do so.[119]

Like Judge Young in the *Nexium* trial, Judge McLaughlin in the *Wellbutrin* case had required plaintiffs proceeding on a zero-payment alternative settlement theory to produce proof that such a settlement was actually feasible.[120] Instead of sending the issue to the jury, however, she granted summary judgment for the defendants.[121] The judge cited evidence that the generic drug manufacturer had "expressly and unwaveringly refused to settle

115. *See Nexium*, 842 F.3d at 49-51.

116. *See id.* at 50-51 (quoting the verdict form).

117. *See id.* at 50 (quoting the district court's instructions to the jury).

118. *See id.* at 60 (explaining that the plaintiffs needed to prove that one of the settling parties "would have launched a generic earlier" than the agreed-upon date "but for the antitrust violation found in" the jury's responses to the previous questions on the verdict form). The court rejected Judge Young's explanation that "affirmative answers to [the previous questions on the verdict form] do *not* support a finding of an antitrust violation," *In re* Nexium (Esomeprazole) Antitrust Litig., 309 F.R.D. 107, 142 (D. Mass. 2015) (emphasis added), *aff'd*, 842 F.3d 34 (1st Cir. 2016), instead explaining that the jury's answers "confirm[ed] its finding that some antitrust violation resulted from the [challenged] settlement." *See Nexium*, 842 F.3d at 60.

119. *See Nexium*, 842 F.3d at 54-55, 65 (referring to defense testimony that the brand-name pharmaceutical company had never revealed any willingness to agree to any entry date other than the one allowed for under the challenged settlement).

120. *See In re* Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d 734, 757 (E.D. Pa. 2015), *aff'd*, 868 F.3d 132 (3d Cir. 2017).

121. *See id.* at 737.

[the relevant litigation with the brand-name drug manufacturer] unless the settlement contained" a provision that would benefit the generic manufacturer.[122]

On appeal, the *Wellbutrin* plaintiffs urged the Third Circuit not to engage in a similar assessment of this evidence, explaining that their sole theory of delay was that absent the reverse payment settlement, there would have been an at-risk launch.[123] Presumably the plaintiffs recognized that the court of appeals was unlikely to disagree with the district court's factual assessment, making it all the more important to steer the court away from this portion of the district court's decision. Yet despite not reaching this issue, the Third Circuit's approach is consistent with the district court's: The Third Circuit's emphasis on proving precisely how delay would have materialized[124] would require plaintiffs who did choose to press a zero-payment alternative settlement theory to succeed under an analysis similar to Judge McLaughlin's.

B. A Broader Approach

Several courts have applied an alternative approach. The crucial starting point from which this approach flows is that courts do not require plaintiffs to prove precisely how, absent the illegal settlement agreement, generic entry would have happened earlier. Instead, courts following this approach apply the *Actavis* inference to the causation inquiry, reasoning that a plaintiff who has shown an antitrust violation based on a reverse payment settlement agreement has necessarily shown an agreement to delay generic entry beyond the otherwise expected date.[125] Put another way, instead of requiring plaintiffs to prove which of the three causal paths led to delay, this approach holds that the simultaneous foreclosure of all such paths means that generic entry has, in expectation, been delayed. Having decided that it is unnecessary to inquire into proof for each path, courts following this approach reject the two barriers that stymie private plaintiffs under the narrow approach.[126]

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122. *See id.* at 757. The generic manufacturer had demanded "a no authorized generic agreement." *Id.* The Third Circuit had already held that this type of agreement could be a reverse payment under *Actavis*. *See* King Drug Co. of Florence v. Smithkline Beecham Corp. (*Lamictal*), 791 F.3d 388, 403-10 (3d Cir. 2015).

123. *See* Plaintiffs-Appellants'/Cross-Appellees' Submission of Redacted First- and Third-Step Briefs, *supra* note 89, ex. B at 27 n.97.

124. *See supra* notes 87-90 and accompanying text.

125. *See infra* Part II.B.1.

126. *See infra* Part II.B.2.

1. By proving an antitrust violation, plaintiffs have proved an agreement to delay entry beyond the patent's "expected life had enforcement been sought"

Several courts have rejected defendants' arguments that in order to show that a reverse payment settlement agreement has caused injury to private plaintiffs, plaintiffs must allege and ultimately prove precisely how the agreement foreclosed earlier generic entry. These courts reason that this is the only way to reconcile a private claim with the *Actavis* Court's reasoning that a large, unexplained payment can violate the antitrust laws because it "likely seeks to prevent the *risk* of competition"—even when there is only "a small risk of invalidity."[127]

In the *Cipro* litigation, the California Supreme Court rejected a defendant's argument that plaintiffs had failed to produce enough proof of causation to survive summary judgment.[128] As the court explained, "The measure of the statutory grant [of a patent], and the limit on the monopoly that may be preserved by agreement, is the *average expected duration* that would have resulted from judicial testing."[129] This "expected life had enforcement been sought" forms "the baseline against which the competitive effects of any agreement must be measured."[130] The court explained that an antitrust violation arises when the agreement involves "payment for exclusion beyond the point that would have resulted, on average, from simply litigating the case to its conclusion."[131] Because finding a violation means the factfinder has determined that there was an agreement to delay generic entry beyond the "relevant baseline," the court rejected a defendant's argument "that causation is lacking in reverse payment cases because absent a settlement, the parties would have litigated, the patentee would likely or surely have won, and consumers would have been no better off."[132]

The California Supreme Court explained that its causation approach followed directly from the *Actavis* Court's rationale for liability. Observing that "nothing in [*Actavis*]'s discussion of the legal rules at the boundary between antitrust and patent law hinged on the happenstance that the case under review involved a public prosecutor," the court applied *Actavis*'s insights to its adjudication of a private lawsuit.[133] In so doing, it relied on two of the key

127. *See* FTC v. Actavis, Inc., 133 S. Ct. 2223, 2236 (2013) (emphasis added).

128. *See In re* Cipro Cases I & II, 348 P.3d 845, 853, 870 n.19, 873 (Cal. 2015).

129. *Id.* at 864 (emphasis added).

130. *Id.*

131. *See id.* at 867.

132. *See id.* at 870 & n.19.

133. *See id.* at 858-59.

features of *Actavis* discussed in Part I.A above: (1) litigation of patent validity is unnecessary because "an agreement that 'seeks to prevent the risk of competition' *causes*, i.e., has as a 'consequence . . . the relevant anticompetitive harm'";[134] and (2) an agreement can inflict anticompetitive harm "even when the patent is likely valid."[135]

Several federal district courts have employed similar reasoning to deny reverse payment defendants' motions to dismiss, including Judge Underhill of the District of Connecticut in *Aggrenox*,[136] Judge Leinenweber of the Northern District of Illinois in *Opana*,[137] and Judge DuBois of the Eastern District of Pennsylvania in *Niaspan*.[138] Like the California Supreme Court in *Cipro*, these courts relied on the *Actavis* Court's explanation that the relevant anticompetitive harm follows from an agreement that "seeks to prevent the risk of competition" regardless of the particular probability of validity, rejecting defendants' pleas to require consideration of patent validity as part of the causation inquiry.[139] Two of these courts specifically focused on the "probabilistic" nature of the anticompetitive harm.[140] A different pair expressly noted that their analyses extended to the question of ultimate proof, explaining that plaintiffs do not ultimately need to "plead (or prove) the weakness of the [relevant] patent."[141]

The Second Circuit in *Actos*[142] also endorsed key parts of the reasoning underpinning this approach. Reversing a district court's order granting a motion to dismiss, the panel held that plaintiffs claiming delay induced by fraudulent statements to the FDA need not allege that they will "rule out a

134. *See id.* at 870 n.19 (alteration in original) (emphasis added) (quoting FTC v. Actavis, Inc., 133 S. Ct. 2223, 2236 (2013)).

135. *See id.* at 863 (citing *Actavis*, 133 S. Ct. at 2236).

136. *See In re* Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 241, 257-58 (D. Conn. 2015).

137. *See In re* Opana ER Antitrust Litig., 162 F. Supp. 3d 704, 720, 726 (N.D. Ill. 2016).

138. *See In re* Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 740, 755 (E.D. Pa. 2014). Of course, a judge in the Eastern District of Pennsylvania today would likely need to abandon Judge DuBois's reasoning in *Niaspan* in light of the Third Circuit's decision in *Wellbutrin* endorsing the opposing approach. *See supra* Part II.A.

139. *See Opana*, 162 F. Supp. 3d at 720 (quoting *Actavis*, 133 S. Ct. at 2236); *Aggrenox*, 94 F. Supp. 3d at 240; *Niaspan*, 42 F. Supp. 3d at 755.

140. *See In re* Aggrenox Antitrust Litig., No. 3:14-md-2516 (SRU), 2015 WL 4459607, at *9 (D. Conn. July 21, 2015); *Niaspan*, 42 F. Supp. 3d at 755; *see also Aggrenox*, 94 F. Supp. 3d at 241.

141. *See Aggrenox*, 94 F. Supp. 3d at 240; *see also Opana*, 162 F. Supp. 3d at 720 (relying on *Aggrenox*).

142. United Food & Commercial Workers Local 1776 v. Takeda Am. Holdings (*In re* Actos End-Payor Antitrust Litig.), 848 F.3d 89 (2d Cir. 2017).

litany of alternative possible causes of [a generic manufacturer's] delayed market entry."[143]

Finally, well-regarded antitrust scholars have indicated that they believe this approach arrives at the correct conclusion.[144]

2. Plaintiffs need not produce proof of patent validity or of the likelihood a zero-payment settlement could have been reached

Because courts adopting this broader approach do not require proof of precisely how generic entry would have happened earlier, they also reject the need for the two types of proof demanded by courts following the narrow approach. First, the broader approach squarely rejects the notion that private plaintiffs' ability to prevail hinges on their ability to "plead (or prove) the weakness of the [relevant] patent."[145] Second, under this approach there is no need to know whether a zero-payment alternative settlement containing an earlier entry date was actually feasible. Such an inquiry would only make sense if a plaintiff needed to prove which specific causal mechanism led to delayed entry, but courts following this approach do not demand this proof. Instead, they allow plaintiffs to prove a delay in the expected entry date,[146] meaning

143. *See id.* at 92-93, 100-01. Because the Second Circuit's holding in *Actos* did not address a reverse payment claim, it remains unclear how the Second Circuit would approach the causation question addressed by this Note. One feature of the Second Circuit's approach that might carry over, however, is its suggestion that more proof of causation might be necessary at later trial stages. *See id.* at 101 (suggesting a presumption of causation through the summary judgment stage in cases involving certain conduct).

144. *See, e.g.*, Michael A. Carrier, Essay, *The Curious Case of* Wellbutrin*: How the Third Circuit Mistook Itself for the Supreme Court*, 103 CORNELL L. REV. ONLINE 137, 145 (2018) (criticizing the *Wellbutrin* court for "downplay[ing] the connection between payment and patent weakness and resuscitat[ing] the defense based on risk that the Supreme Court had rejected"); Hovenkamp, *supra* note 26, at 13 ("Under *Actavis*, purchasers seeking antitrust overcharge damages from an anticompetitive pay-for-delay settlement should be able to proceed without proving patent invalidity . . . ."); *see also* AREEDA-HOVENKAMP, *supra* note 3, ¶ 345a, at 67-68 (Supp. 2016) (discussing the calculation of damages in a private reverse payment case where there are "no findings concerning patent validity or infringement" and thus implicitly assuming that such a case is not categorically barred).

145. *See Aggrenox*, 94 F. Supp. 3d at 240; *see also Opana*, 162 F. Supp. 3d at 720 ("Plaintiffs need not plead (or prove) the weakness of the [relevant] patents . . . ."); *Niaspan*, 42 F. Supp. 3d at 755 ("[T]he Court is not convinced that the hurdle of 'antitrust injury' . . . [requires that plaintiffs] allege—and ultimately prove—that, but for the [relevant] settlement agreements . . . , [the generic manufacturer] would have secured a judgment of non-infringement, invalidity, and/or unenforceability of [the relevant] patents."); *In re* Cipro Cases I & II, 348 P.3d 845, 870 (Cal. 2015) ("Agreements must be assessed as of the time they are made, at which point the patent's validity is unknown and unknowable." (citation omitted)).

146. *See Cipro*, 348 P.3d at 867, 870 & n.19.

that absent the settlement a generic can be expected to have launched "earlier than it finally did either: (a) 'at-risk' (that is, while the patent litigation was still pending); (b) after winning the patent suit; or (c) via a lawful settlement agreement that provided for an earlier [generic] entry date without a large reverse payment."[147] As a result, the broader approach eliminates the ultimate bite of the narrow approach.

While the courts following the broader approach provide an important alternative to the narrow approach, it is worth taking account of two recent federal district court decisions that do not fully conform to either of the two approaches described above. In *Lidoderm*, Judge Orrick of the Northern District of California denied summary judgment to defendants who had urged the court to adopt the *Wellbutrin* and *Nexium* formulation of causation.[148] In so doing, Judge Orrick rejected several key building blocks of the narrow approach, including: (1) "reliance on the FTC being the plaintiff in *Actavis* to discount the 'large and unexplained' reverse payment proxy for patent weakness standard adopted by the *Actavis* majority";[149] (2) the argument "that plaintiffs need to prove *in this case* that [the generic challenger] *would have* won its patent litigations," which the court labeled an "unappetizing" "turducken";[150] and (3) the proposition that under a zero-payment alternative settlement theory, it is categorically impermissible to infer delay "from the existence of [an] unjustified large reverse payment."[151] Despite these key differences from the narrow approach, the judge did not reject the premise that plaintiffs must prove a specific theory of causation; instead, he separately evaluated the plaintiffs' proof for each of two theories (at-risk launch and zero-payment alternative settlement) and concluded that there was enough to survive summary judgment under both theories.[152]

Judge Casper of the District of Massachusetts recently applied a similar standard in *Solodyn* and concluded that there was enough evidence to go to trial

147. *See Opana*, 162 F. Supp. 3d at 720.

148. *See* United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA (*Lidoderm*), No. 14-md-02521-WHO, 2017 WL 5068533, at *1-3, *10-11, *13 (N.D. Cal. Nov. 3, 2017).

149. *Id.* at *4.

150. *Id.* at *5.

151. *See id.* at *11 (indicating that the basis for the defendants' challenge to one of the plaintiffs' expert reports was the report's reliance on this inference); *id.* at *13 (denying the defendants' motion for summary judgment on the plaintiffs' alternative settlement causation theory).

152. *See id.* at *2, *10, *13. The decision suggests that the court may have been following the plaintiffs' lead in conducting separate analysis for each of these two theories. *See id.* at *2 (citing the plaintiffs' brief as support for the point that "[p]laintiffs' case rests on two theories of antitrust injury causation").

on these two theories.[153] On the whole, these two summary judgment orders reach the result required by the broader approach and adopt some of its key reasoning, but both hedge by citing narrow approach cases as if there were no inconsistency.[154] Stitching together these fundamentally inconsistent legal approaches creates an unstable Frankenstein standard for causation. To take just one example of why this approach does not work, note that the *Lidoderm* and *Solodyn* courts extracted from the First Circuit's *Nexium* decision a "some evidence" standard for patent merits that squarely conflicts with the Third Circuit's *Wellbutrin* decision[155]—even though the First and Third Circuits are

153. *See In re* Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-md-02503, 2018 WL 563144, at *13-16, *21-23 (D. Mass. Jan. 25, 2018).

154. *Lidoderm* is representative here. In addition to accepting the narrow approach's premise that each theory of causation should be evaluated separately, the court asserted that its reasoning was consistent with aspects of the narrow approach within each theory. First, in its at-risk launch analysis, the court held that while plaintiffs need not show that the generic manufacturer *would have* prevailed in the patent litigation, they nonetheless "must show '*some evidence*' that [the generic manufacturer] *could have* won" the patent litigation. *See Lidoderm*, 2017 WL 5068533, at *5 (emphasis added) (quoting Am. Sales Co. v. AstraZeneca LP (*In re* Nexium (Esomeprazole) Antitrust Litig.), 842 F.3d 34, 63 (1st Cir. 2016)). While the court indicated that it derived this lower-than-preponderance standard for patent merits from *Nexium*, its approach in fact requires a strained reading of language from the *Nexium* decision that could instead be read to require proof by a *preponderance of the evidence* that the generic manufacturer *would have* succeeded in its patent case. *See supra* note 100 and accompanying text; *see also* Am. Sales Co. v. AstraZeneca LP (*In re* Nexium (Esomeprazole) Antitrust Litig.), 845 F.3d 470, 475 (1st Cir. 2017); *Nexium*, 842 F.3d at 63. Whatever may be made of *Nexium*, there is no room for doubt that the *Lidoderm* standard is inconsistent with *Wellbutrin* as well as with Thomas et al.'s commentary, both of which adopt a preponderance standard. *See supra* notes 100-01 and accompanying text; *see also In re* Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 166, 169 (3d Cir. 2017); Thomas et al., *supra* note 25.

Second, in its "alternative settlement" analysis, the court purported to apply *Wellbutrin*, explaining that this theory had merely been "rejected . . . on the facts of [the] case" there. *See Lidoderm*, 2017 WL 5068533, at *10. But the evidence the *Lidoderm* court cited as sufficient to survive summary judgment is of an entirely different nature than the evidence the *Wellbutrin* district court found sufficient to defeat causation as a matter of law. The *Lidoderm* court properly pointed to expert economists' analysis showing what would have been contained in a hypothetical zero-payment agreement, including the baseline date relevant for calculating damages. *See id.* at *11-13; *see also infra* notes 198-201 and accompanying text (explaining how the correct approach incorporates analysis of a hypothetical alternative settlement). In *Wellbutrin*, the district court improperly relied on evidence about the settling parties' actual stances in negotiations. *See In re* Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d 734, 757 (E.D. Pa. 2015), *aff'd*, 868 F.3d 132 (3d Cir. 2017); *see also infra* notes 196-97, 201 and accompanying text (explaining why the correct approach treats such evidence as irrelevant).

155. *Compare Lidoderm*, 2017 WL 5068533, at *4 ("'Some evidence' is not the same as requiring plaintiffs to prove that the generic defendant *would have* won, only that it *could have*." (quoting *Nexium*, 845 F.3d at 63)), *and Solodyn*, 2018 WL 563144, at *14 (adopting this reasoning), *with Wellbutrin*, 868 F.3d at 166 (requiring proof that "but for

footnote continued on next page

best understood as falling on the same side of the key divide here.[156] More fundamentally, these courts' hesitation to unreservedly embrace the broader approach demonstrates the pernicious influence the narrow approach will have if left unchecked.

C. A Genuine Conflict

While this Note joins one other piece of commentary in recognizing that these courts have taken fundamentally divergent approaches,[157] some courts have already planted the seeds of resistance to the notion that there is a split here. Three objections may become prominent; none is compelling.

First, there may be some inclination to distinguish the *Cipro* analysis on the basis that it interprets California's Cartwright Act, not the federal Clayton Act.[158] But nothing in *Cipro* hinged on the distinction between injury "by reason of" a federal antitrust violation and injury "by reason of" a California Cartwright Act violation.[159] Instead, the *Cipro* court supported its rejection of the "scope of the patent" test with references to and reliance on *Actavis*.[160] Moreover, a single federal court may find itself adjudicating both a federal antitrust claim and a Cartwright Act claim. That court should not be required to draw an unprincipled distinction between the causation analyses for the two claims. Any differences between federal and state antitrust law should flow from a state's deliberate departure from the federal rule,[161] not from a state's

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the challenged agreements, [the generic manufacturer] *would have* been able to launch its [competing product] without running afoul of [the relevant] patent" (emphasis added)), *and id.* at 169 (relying on an expert's analysis that the generic manufacturer "would only have a 20% chance of winning" the patent suit to support the conclusion that there was insufficient evidence to survive summary judgment).

156. *See supra* Part II.A.

157. *See* Thomas et al., *supra* note 25.

158. *See, e.g.*, *Wellbutrin*, 133 F. Supp. 3d at 756 & n.35, 762-63 (reasoning that the causation inquiry might be different under the Cartwright Act than under the Clayton Act); *see also* Cartwright Act, ch. 526, § 1, pt. 2, ch. 2, 1941 Cal. Stat. 1834, 1834-38 (codified as amended at CAL. BUS. & PROF. CODE §§ 16700-16761 (West 2018)).

159. *See* 15 U.S.C. § 15(a) (2016); CAL. BUS. & PROF. CODE § 16750(a).

160. *See In re* Cipro Cases I & II, 348 P.3d 845, 861 (Cal. 2015) ("[W]e conclude the scope of the patent test is inapplicable to Cartwright Act claims."); *id.* at 864 ("*Actavis* makes clear that for antitrust purposes patents are no longer to be treated as presumptively ironclad."); *id.* at 870 n.19 (relying on *Actavis* to explain why doubts about patent validity do not interfere with causation); *see also* Simmons et al., *supra* note 21, at 26 ("[T]he same patent issues affecting Clayton Act litigation—namely the validity and scope of an underlying patent—will impact private litigation under the Cartwright Act as well.").

161. *Cf.* California v. ARC Am. Corp., 490 U.S. 93, 100-01 (1989) (holding that "express state statutory provisions" recognizing a cause of action unavailable under federal antitrust law are not preempted by federal law).

application of the federal rule—as was the case in *Cipro*. And whatever the causation standard might be under federal law, a federal court engages in nothing short of blatant misapplication of state law when it adjudicates California law claims under the narrow causation approach *Cipro* rejected—as the Third Circuit did in *Wellbutrin*.[162]

Second, one might follow the *Nexium* panel's lead and distinguish analysis that appears in adjudications of motions to dismiss as less relevant to matters of ultimate proof.[163] A similar argument might be advanced in an effort to put distance between *Opana* and *Aggrenox* (decided on motions to dismiss) and *Nexium* and *Wellbutrin* (decided at later trial stages). But that distinction is meaningless with respect to the split discussed here: The *Opana* and *Aggrenox* district courts' reasoning turns on what plaintiffs ultimately need to prove, not merely how they must plead—as those courts expressly indicated.[164]

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162. *See In re* Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 163 n.53 (3d Cir. 2017) (indicating that California's requirements for antitrust standing and injury "appear to be" indistinguishable from the federal standard). The Third Circuit's bungling of California law led the state's Attorney General to file an amicus brief urging the court to certify a question about the proper California causation standard to the California Supreme Court. *See* Brief of the State of California as Amicus Curiae Requesting Panel's Certification of State Law Question to the California Supreme Court in Support of Plaintiff-Appellants' Petitions for Rehearing and Rehearing En Banc at 1-3, 6-9, *In re* Wellbutrin XL Antitrust Litig., Nos. 15-3559 et al. (3d Cir. Sept. 7, 2017), 2017 WL 4004875; *see also* Petition for Panel Rehearing of Indirect Purchaser Class Plaintiff-Appellants' California State Law Claims at 10-12, *Wellbutrin*, Nos. 15-3559 et al. (3d Cir. Aug. 31, 2017) (making a similar argument for rehearing).

This effort was unsuccessful. The Third Circuit denied panel rehearing and rehearing en banc without comment. *See* Order Sur Petition for Rehearing, Nos. 15-2875 et al. (3d Cir. Sept. 20, 2017). Although it may not be possible to fully understand how the Third Circuit's panel decision could include such a clear misstatement of the governing law, one plausible explanation is that the plaintiffs' briefing does not appear to call explicit attention to the issue. *See* Plaintiffs-Appellants'/Cross-Appellees' Submission of Redacted First- and Third-Step Briefs, *supra* note 89, ex. A at 80 & n.396. The plaintiffs cited *Cipro* in support of their causation position without noting that the case included binding causation precedent with respect to California state law claims and without calling attention to footnote nineteen of *Cipro*—where the California Supreme Court had expressly rejected the narrow causation approach. *See id.*; *see also Cipro*, 348 P.3d at 870 n.19.

163. *See* Am. Sales Co. v. AstraZeneca LP (*In re* Nexium (Esomeprazole) Antitrust Litig.), 842 F.3d 34, 62-63 (1st Cir. 2016) (distinguishing two pre-*Actavis* cases on the basis that they were decided at the motion to dismiss stage); *see also Wellbutrin*, 133 F. Supp. 3d at 765 n.46 (same).

164. *See In re* Opana ER Antitrust Litig., 162 F. Supp. 3d 704, 720 (N.D. Ill. 2016) ("Plaintiffs need not plead (*or prove*) the weakness of the [relevant] patents . . . ." (emphasis added)); *In re* Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 240 (D. Conn. 2015) ("The plaintiffs thus need not plead (*or prove*) the weakness of the [relevant] patent . . . ." (emphasis added)).

Third, a skeptic about the split might latch on to language in *Nexium* and *Wellbutrin* that, taken out of context, suggests that relevant portions of those decisions contain no broad legal conclusions, but rather only factual conclusions specific to those cases.[165] But as the above discussion demonstrates, the legal decision to require proof of the specific mechanism by which earlier entry would have occurred is the point at which the approaches diverge. And even if that point of divergence were treated as inessential, the disparity it helps explain would remain: The narrow approach requires proof where the broader approach requires none.[166] In any event, the only factual nuances the *Wellbutrin* and *Nexium* courts point to arise in the course of examining the proof this approach demands, not in the course of determining whether the examination will be necessary in the first place.

III. Why the Broader Approach to Private Recovery Is Correct

The approaches described above differ dramatically in the justifications they claim and the outcomes they reach. Under the narrow approach to causation, an antitrust violation like the one at issue in *Actavis* is largely unenforceable by a private party.[167] Under the broader approach, a relatively robust remedy exists. This Part explains why the latter approach is more consistent with doctrine and policy.

A. The Narrow Approach Misunderstands *Actavis*

After requiring plaintiffs to pick a causal mechanism and prove it, courts following the narrow approach have required proof that either (1) the patent underlying the reverse payment agreement is invalid or (2) the parties to the agreement would otherwise have been willing to agree to a zero-payment settlement. Neither hurdle should exist.

165. *See Wellbutrin*, 868 F.3d at 166-68 (characterizing the plaintiffs' argument that patent weakness could be inferred from the reverse payment as part of their "factual response" to the conclusion that the relevant patent would block earlier entry); Am. Sales Co. v. AstraZeneca LP (*In re* Nexium (Esomeprazole) Antitrust Litig.), 845 F.3d 470, 475 (1st Cir. 2017) ("All the panel's holding did was recognize that, given the peculiarities of this case, the district court in no way forced a 'detailed exploration' of patent validity within an antitrust case." (quoting FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013))).

166. The *Lidoderm* summary judgment order illustrates this point. Whereas that court accepted the narrow approach's premise that plaintiffs must support a specific causation path with specific proof, the court relied for its holding on several legal distinctions from the narrow approach. *See supra* notes 149-56 and accompanying text.

167. *See supra* notes 106-14 and accompanying text.

1. The problems of proving patent invalidity in a private plaintiff antitrust suit

As discussed in Part II.B above, the *Actavis* Court explained that "the relevant anticompetitive harm" from an illegal reverse payment settlement agreement is that it "likely seeks to prevent the risk of competition."[168] Because these anticompetitive effects can be inferred from the size of the unjustified payment, "it is normally not necessary to litigate patent validity to answer the antitrust question."[169] Indeed, the Court made clear that actual patent invalidity is not the source of anticompetitive effects when it expressly noted that nothing about the antitrust violation turns on the particular probability that a patent will be invalidated: A large, unexplained payment by a brand that owns a "particularly valuable patent" with "even a small risk of invalidity" nonetheless can indicate an anticompetitive agreement.[170]

The causation inquiry is no different in this respect. Just as anticompetitive effects attach to a reverse payment "even when the patent is likely valid,"[171] so too can that payment cause injury-in-fact regardless of the particular probability that the underlying patent was valid. This result follows from the logic underpinning *Actavis*. Recall the version of the stylized example discussed in Part I.A.2 above in which the probability of invalidity of a patent with ten remaining years is 40%. As explained there, an illegal payment in exchange for delay in entry can still deprive consumers of up to four years of a competitive market. Ending the inquiry in a private case after a less-than-50% probability of invalidity has been established—as the *Wellbutrin* court did when it relied on a 20% probability to justify its holding[172]—is irreconcilable with the *Actavis* Court's observation that a small risk of invalidity can be sufficient to prove anticompetitive harm.[173] Nothing about the harm caused to private plaintiffs from four years of delay turns on the fact that the patent is more likely than not valid; it was still wielded impermissibly to buy delay at consumers' expense. Instead of ending the inquiry, the less-than-50% probability of invalidity is merely an input useful for calculating the expected entry date absent the illegal agreement and therefore useful for calculating damages. Courts adopting the narrow causation approach are thus mistaken to

168. *See Actavis*, 133 S. Ct. at 2236.

169. *See id.*

170. *See id.*

171. *In re* Cipro Cases I & II, 348 P.3d 845, 863 (Cal. 2015) (citing *Actavis*, 133 S. Ct. at 2236).

172. *See In re* Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 169 (3d Cir. 2017).

173. *See Actavis*, 133 S. Ct. at 2236.

treat any standalone finding about the likelihood of validity as a barrier to causation.[174]

Treating patent validity as the be-all and end-all for private plaintiffs, as the narrow approach does, thus misses the forest for the trees. After observing that private plaintiffs must show something about causation whereas the government need not, courts adhering to this approach put forward precisely the arguments the *Actavis* Court rejected. For instance, just as the *Actavis* dissent objected to "impos[ing] antitrust liability based on the parties' subjective uncertainty about" patent validity,[175] the narrow causation approach resists the inference of anticompetitive effects from an agreement reached under uncertainty about validity, instead requiring plaintiffs to produce proof of patent invalidity.[176] And just as the *Actavis* dissent critiqued the Court's "assumption that offering a 'large' sum is reliable evidence that the patent

174. This is not to say that the inference of anticompetitive harm from a reverse payment will be correct every time. Rather, the point is that the *Actavis* inference is settled law (because the Court held it to be a good enough way to establish anticompetitive harm), and courts should therefore vigilantly weed out and reject formulations of causation that relitigate the inference. This is a mandate the Third Circuit appeared to neglect in *Wellbutrin*. That court explained it had been "persuaded by an argument raised in [an] amicus brief filed by a group of antitrust economists"; the brief "explains why risk aversion makes it difficult to use the size of a settlement as a proxy for the brand-name's likelihood of success in litigation." *Wellbutrin*, 868 F.3d at 168. This group of economists may very well have a point, but it is the same point—entirely about the wisdom of inferring anticompetitive effects from a reverse payment—the *Actavis* Court rejected when it indicated that "the relevant anticompetitive harm" is prevention of the "risk of competition." *See Actavis*, 133 S. Ct. at 2236; *see also* Carrier, *supra* note 144, at 145. Indeed, six of the twelve economists who signed the *Wellbutrin* brief had invoked the same arguments in a brief they signed in *Actavis*, deploying those points in that case to explain why reverse payment agreements ought to escape rigorous antitrust scrutiny altogether. *Compare* Brief of Antitrust Economists as Amici Curiae in Support of Defendants-Appellees at 3, *Wellbutrin*, 868 F.3d 132 (Nos. 15-3559 & 15-3681) ("[E]conomic principles illuminate many reasons other than delay as to why a patent holder might provide consideration to a patent challenger as part of a settlement agreement . . . ."), *and id.* app. A (listing signatories), *with* Brief of Antitrust Economists as Amici Curiae in Support of Respondents at 3, *Actavis*, 133 S. Ct. 2223 (No. 12-416), 2013 WL 836946 ("Reverse payments in patent settlements can occur for a variety of reasons having nothing to do with payment for delaying entry."), *and id.* app. A (listing signatories).

175. *See Actavis*, 133 S. Ct. at 2244 (Roberts, C.J., dissenting).

176. *See Wellbutrin*, 868 F.3d at 165 (requiring plaintiffs to show that earlier entry "would have been legal" and would not have been "effectively blocked by federal patent law"); *see also* Am. Sales Co. v. AstraZeneca LP (*In re* Nexium (Esomeprazole) Antitrust Litig.), 842 F.3d 34, 63 (1st Cir. 2016) (affirming the district court's reasoning that plaintiffs would need "to overcome the likelihood that [the relevant] patents, not [the] reverse payment . . . , were the bar to a generic launch"); Simmons et al., *supra* note 21, at 26 ("[S]ome form of patent analysis and litigation is necessary in private actions post-*Actavis* if the defense asserts that it was the branded company's patents that foreclosed the generic company's market entry.").

holder has serious doubts about the patent,"[177] so too does the narrow approach decline to "view the size of the reverse payment as 'a surrogate for [the] patent's weakness.'"[178] Reviving those arguments here, and requiring litigation of validity in many private claims, is "dissonant with the [*Actavis*] decision's reasoning and on the whole a very unlikely interpretation" of the case.[179]

By brushing these concerns aside, the narrow approach requires an implausible reading of the *Actavis* Court's indication that "it is normally not necessary to litigate patent validity."[180] That statement is not a mere stray comment. Indeed, it is essentially a way of phrasing the Court's holding. The reason patent validity normally need not be litigated is that anticompetitive effects can be inferred from the terms of a reverse payment settlement agreement, as the Court explained in the balance of its decision.[181] Indeed, the Court immediately clarified that the principal example making the qualifier "normally" necessary is not a reverse payment claim, but rather a sham litigation claim.[182] This contrasts sharply with the "scope of the patent" test the Court rejected. Patent validity played a pivotal role in that approach's two-step logic for tossing out reverse payment claims: Only an agreement outside the scope of a valid patent could be anticompetitive, and patents whose validity was unknown at the time of the agreement were bestowed an irrebuttable presumption of validity in the antitrust suit.[183] Glossing over this key part of *Actavis* as merely a prediction about future cases, as the *Wellbutrin* court does, therefore results in a failure to faithfully apply *Actavis*'s "controlling

177. *Actavis*, 133 S. Ct. at 2244 (Roberts, C.J., dissenting).

178. *See Wellbutrin*, 868 F.3d at 168 (alteration in original) (quoting the plaintiffs' opening brief). The court's skepticism about drawing an inference of anticompetitive harm from the reverse payment at issue in *Wellbutrin* is particularly puzzling. The court suggested that the payment may not have indicated that the brand-name company was uncertain about patent strength because the company may have instead made the payment out of fear that the generic manufacturer "would improperly evaluate the patent and launch at-risk." *See id.* But this is precisely the type of risk antitrust laws forbid a company from paying to eliminate: the risk that the competitor will enter the market earlier than the incumbent firm would like. It is of course perfectly rational for a company to want to make this payment, but that does not make it legal for it to do so.

179. *See In re* Aggrenox Antitrust Litig., No. 3:14-md-2516 (SRU), 2015 WL 4459607, at *9 (D. Conn. July 21, 2015).

180. 133 S. Ct. at 2236 (majority opinion).

181. *See* Edlin et al., *supra* note 26, at 587 ("According to *Actavis*, the trial court need not determine validity or infringement of the patent in order to assess the legality of a reverse payment settlement under the antitrust laws."); *see also id.* at 589 (describing the *Actavis* inference as the inference of anticompetitive effects from evidence that does not include patent validity).

182. *See Actavis*, 133 S. Ct. at 2236.

183. FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1308, 1312 (11th Cir. 2012), *rev'd and remanded sub nom. Actavis*, 133 S. Ct. 2223.

precedent"—something particularly concerning when it comes from a court that barely conceals its preference for the dissent's analysis over the majority's.[184]

The implausible reading of *Actavis* is particularly problematic because under that reading, the case has "no practical application except in suits by the government."[185] But "nothing in [*Actavis*]'s discussion of the legal rules at the boundary between antitrust and patent law hinged on the happenstance that the case under review involved a public prosecutor."[186] Proponents of the narrow approach fail to identify any suitably weighty justification for effectively foreclosing private recovery.[187]

In addition to unjustifiably reducing deterrence and compensation, the narrow approach creates an odd asymmetry in recovery even if private plaintiffs are permitted to litigate validity within their antitrust suits—which is by no means clear.[188] By assumption, the parties to a reverse payment settlement condemned under *Actavis* do not know at the time of their illegal settlement whether the contested patent is valid.[189] So an approach that metes out antitrust recoveries based on ex post information about actual validity would require different treatment for similar agreements.[190] Suppose, for example, that the parties to a settlement correctly identify the probability of invalidity of a patent expiring in ten years as 50%, but the generic manufacturer agrees, in exchange for a payment, to delay entry until seven years after the settlement. For every two such agreements, this theory says that one (the one

184. *See Wellbutrin*, 868 F.3d at 162 n.50 (highlighting Chief Justice Roberts's "cogent criticism" before indicating that "the controlling precedent is what it is"); *id.* at 167 n.58 (justifying the decision to investigate patent validity as a precondition for causation in part based on the tautological assertion that "[t]he present case appears to vindicate the Chief Justice's" argument that such an investigation should usually be necessary); *see also* Carrier, *supra* note 144, at 141 ("[T]he [*Wellbutrin*] court's level of remorse at reaching [the correct result on one particular issue] was striking . . . .").

185. *See Aggrenox*, 2015 WL 4459607, at *9.

186. *In re* Cipro Cases I & II, 348 P.3d 845, 858-59 (Cal. 2015).

187. *See supra* notes 110-13 and accompanying text.

188. *See supra* notes 102-05 and accompanying text.

189. *See supra* note 36 and accompanying text.

190. *Cf.* 1 HOVENKAMP ET AL., *supra* note 8, § 16.01[D], at 16-30 ("[T]he correct analysis for exclusion payment settlements is based on the ex ante assessment of the patent's validity, not on how the patent ultimately fares ex post in the courts."). For further discussion of this point, see *In re* Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 241 (D. Conn. 2015); *Cipro*, 348 P.3d at 870; and Edlin et al., *supra* note 26, at 617. Even if there were some role for an ex post assessment of validity, there are good reasons to suspect that such an assessment would be unreliable. *See* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 73 (2009) ("After a case settles, the parties' interests become aligned, with a generic firm lacking the incentive to vigorously attack a patent's validity or an infringement claim.").

where the patent is actually invalid) supports an antitrust claim, while the other does not. But the one that supports a claim will be found to support damages for seven years of delay, while the other requires judgment for the defendants. Far better to allow the plaintiffs in both cases to recover for the harm of no competition in years six and seven than to award a windfall to the first plaintiff while handing the second an unfair defeat.[191]

2. Rewarding defendants for their own intransigence: the consequences of requiring proof of the feasibility of a zero-payment alternative settlement

When courts demand proof that the parties to a reverse payment settlement would have actually agreed to a settlement with an earlier entry date but without the reverse payment,[192] they are seeking proof that is superfluous to the proper inquiry. Part III.B below explains why the proper inquiry omits this question as well as what the inquiry should look like instead. But it is worth first pausing to note that by asking this superfluous question, the narrow approach creates dangerous incentives and produces unfair results.

Consider what this inquiry looks like. In *Nexium*, the court asked the jury to "suppose [the brand-name and generic manufacturers] were settling straight up without any anticompetitive effects" and then assess whether "that settlement license entry date [would] have been earlier than the date they agreed to."[193] After hearing two defense witnesses testify that the brand-name pharmaceutical company never revealed any willingness to agree to any entry date other than the one allowed for under the challenged settlement,[194] the jury was given ample reason to find that the parties would not have actually reached such a "straight up" settlement. And in *Wellbutrin*, the district court (in a portion of its decision not directly implicated in the appeal to the Third Circuit) found that the evidence that the parties themselves would not have entered into any alternative agreement was so compelling as to warrant summary judgment for the defendants.[195]

At bottom, this inquiry—by according weight to evidence like a settling pharmaceutical company's "express[] and unwavering[]" insistence on receiving

191. As this example illustrates, results could also differ dramatically in the aggregate. That is, the approach creates windfalls in some cases and unfair defeats in others, but the net result is not guaranteed to even out.

192. *See supra* Part II.A.2.

193. *See* Am. Sales Co. v. AstraZeneca LP (*In re* Nexium (Esomeprazole) Antitrust Litig.), 842 F.3d 34, 50 (1st Cir. 2016) (quoting the district court's instructions to the jury).

194. *See id.* at 54-55.

195. *See In re* Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d 734, 737-38 (E.D. Pa. 2015), *aff'd in other part*, 868 F.3d 132 (3d Cir. 2017); *supra* notes 120-24 and accompanying text.

a reverse payment as a condition of settlement[196]—credits defendants' steadfast commitment to violating antitrust law as a reason to deny antitrust relief. Such a rule tells defendants that all they need to do to avoid liability is to insist in settlement talks that the only agreement they would make is an illegal one. This rule fuses that dangerous incentive with an unfair result for plaintiffs. By showing an illegal agreement to delay entry past the otherwise-expected date, plaintiffs have demonstrated that they have been harmed—notwithstanding what some alternative settlement between these particular defendants might have looked like.[197] Demanding more would be like requiring proof that companies that collude to allocate a market would have otherwise made some explicit agreement not to allocate the market.

This is not to say that there is no possible role in the analysis for a hypothetical zero-payment settlement agreement. In fact, constructing a hypothetical zero-payment settlement is one way to conceptualize the "relevant baseline" date.[198] Because that date represents the patent's "expected life had enforcement been sought,"[199] one way to understand what the competitive landscape would have looked like but for the illegal agreement is to suppose that the parties had crafted a zero-payment agreement that allowed for entry on that baseline date.[200] But the point of this exercise is to identify the expected entry date absent the illegal agreement, not to show that an alternative agreement would actually have been the mechanism through which that earlier entry date was to be achieved. Moreover, the appropriate analysis brings with it a crucial methodological distinction: What the parties subjectively would have agreed to is irrelevant because the focus is instead on what date reasonable, well-informed negotiators in a similar position would have agreed to.[201]

196. *See Wellbutrin*, 133 F. Supp. 3d at 757 (discussing a company's refusal to settle "unless the settlement contained a no authorized generic agreement").

197. *See infra* Part III.B.

198. *See In re* Cipro Cases I & II, 348 P.3d 845, 864 n.10, 870 (Cal. 2015).

199. *See id.* at 864.

200. Such a zero-payment agreement would "ordinarily" not present an antitrust concern. *See* 1 HOVENKAMP ET AL., *supra* note 8, § 16.01[F].

201. An analogy can be drawn here to the reasonable royalty calculation for patent damages. That analysis assumes a hypothetical negotiation in which the parties were forced to come to a deal; a party's refusal to negotiate is irrelevant. *See* John C. Jarosz & Michael J. Chapman, *The Hypothetical Negotiation and Reasonable Royalty Damages: The Tail Wagging the Dog*, 16 STAN. TECH. L. REV. 769, 783 (2013); *see also* Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1324-25 (Fed. Cir. 2009) (explaining that the hypothetical negotiation assumes willing parties).

B. The Nexus Between the *Actavis* Inference and Causation

Establishing an antitrust violation under *Actavis*'s rule of reason for a reverse payment settlement agreement carries with it a causal conclusion: But for the reverse payment, the expected outcome would have been better for consumers. As explained in Parts I.A and II.B above, an agreement that delays generic entry past the "expected life" of the patent is anticompetitive because it "seeks to prevent the *risk* of competition."[202] That harm does not depend on how the patent dispute would have proceeded absent the settlement. Rather, the agreement has definitively foreclosed competition for the period that runs from the otherwise-expected entry date until the entry date allowed by the agreement.[203] The narrow approach to causation therefore errs when it insists that plaintiffs prove precisely how generic entry would have happened earlier. Consumers who have paid a higher price as a result of delay beyond the otherwise-expected entry date have suffered injury for which the antitrust laws require compensation.

The causation inquiry in a reverse payment case should thus mirror what a court would do if it were evaluating an agreement under which a holder of a valid patent and a rival collude to exclude the rival for some period beyond the life of the patent. An *Actavis* injury is, properly understood, functionally equivalent. In light of the need to estimate an expected entry date, the primary complexity raised by an illegal reverse payment settlement is not *whether* private plaintiffs should recover for the antitrust violation, but *how much*—a question courts never reach when they misconstrue causation.[204]

In addition to following straightforwardly from *Actavis*, this result is consistent with the reasons private plaintiffs must establish antitrust standing. As the Areeda-Hovenkamp treatise points out:

> Treble damages under the antitrust laws serve not only to compensate injured plaintiffs, but also to punish wrongdoers and enlist private plaintiffs in the work of detecting, punishing, and thereby deterring wrongdoing. If this public function of private damage actions is not to be frustrated, courts must not insist upon unduly rigorous proof of the quantum of the plaintiff's injury, for the marketplace usually denies us sure knowledge of what the plaintiff's situation would have been in the absence of the defendant's antitrust violation.[205]

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202. *See Cipro*, 348 P.3d at 864, 870 & n.19 (emphasis added) (quoting FTC v. Actavis, Inc., 133 S. Ct. 2223, 2236 (2013)).

203. *See supra* text accompanying notes 130-32.

204. Of course, a plaintiff who cannot establish a level of damages beyond mere speculation will be unable to recover. *See supra* note 69. But this should not be a categorical bar to recovery for reverse payment plaintiffs. *See supra* note 76.

205. 2A AREEDA-HOVENKAMP, *supra* note 3, ¶ 340a, at 147 (4th ed. 2014).

Though the role of "[t]he individual as a 'private attorney general'"[206] should not be confused with the function of a public enforcer, it is also crucial not to downplay the simultaneous goals of deterrence and compensation accomplished by private antitrust lawsuits. Private plaintiffs are hardly awarded "damages that do not exist"[207] when they are compensated for overpaying a company that has colluded with a potential competitor to delay that competitor's entry into the market. Indeed, awarding no damages at all to such plaintiffs ignores the need to pay "careful attention to the relationship between damage awards and the rationales for finding substantive liability."[208] Courts should be particularly wary of assuming, as the narrow approach must,[209] that adequate deterrence and compensation for a reverse payment settlement agreement can be achieved primarily through government enforcement actions.

To be sure, causation is a freestanding hurdle private plaintiffs must clear; there is no free pass for plaintiffs that applies to only some types of antitrust violations. But advocates of the narrow causation approach are wrong to imply that their approach follows from the mere fact that plaintiffs have *something* extra to prove.[210] Instead of undermining the *Actavis* inference and sidestepping the probabilistic reasoning at the heart of *Actavis* (as the narrow approach does), the correct view recognizes the equivalence between an illegal reverse payment settlement and any other agreement to delay entry past a specific date.

This analogy to a more straightforward context reveals that there should be no need to break any new, reverse payment-specific ground to conduct a proper causation inquiry. Perhaps for this reason, the courts that have correctly adopted the broader approach have not discussed lingering causation

206. *Id.* ¶ 340e, at 179.

207. *Id.*

208. *See id.* ¶ 340a, at 149.

209. *See supra* text accompanying notes 185-87.

210. *See* Simmons et al., *supra* note 21, at 26 ("Because *Actavis* considered only Section 5 of the FTC Act, it did nothing to alter the Clayton Act's causation and injury requirements."); Thomas et al., *supra* note 25 ("[U]nlike the FTC Act, the Clayton Act *does* require plaintiffs to establish an injury-in-fact."); *see also In re* Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d 734, 764 (E.D. Pa. 2015) ("[T]he Clayton Act does demand . . . an analysis [of patent validity], and nothing in *Actavis* altered the Clayton Act's causation requirement."), *aff'd*, 868 F.3d 132 (3d Cir. 2017). Contrast this with the broader approach. *See, e.g.*, *In re* Aggrenox Antitrust Litig., No. 3:14-md-2516 (SRU), 2015 WL 4459607, at *8-9 (D. Conn. July 21, 2015) (rejecting the defendants' argument that the judge had "seemed to collapse the [causation and liability] private-action requirements, which ought to remain distinct," and instead "agree[ing] with the defendants that the plaintiffs must plead and ultimately prove that they have been injured" but reasoning that the judge's approach "does not contradict that requirement").

impediments.[211] That said, courts should be prepared to assess other types of evidence that settling parties will likely suggest interfere with causation.

Two lingering causation concerns warrant consideration. First, there could be an ex ante defect with regard to causation. Here, that would mean that an agreement whose intent was to delay entry was doomed from the outset to fail at achieving that illegal goal—say, because the generic parties to the settlement never had the capacity to enter the market in the first place and somehow bluffed their way into lucrative reverse payments.[212] If this can be sufficiently proved, no one has been injured by the agreement. Second, it is possible that even when a particular agreement gets past the hurdle of this ex ante assessment, the planned delay might nonetheless be thwarted ex post. If, for example, a generic competitor who was not a party to the settlement agreement managed to enter the market despite the agreement, this development could—in conjunction with a showing that prices actually stayed at or below where they would have been in expectation absent the reverse payment agreement—demonstrate that no purchasers suffered any harm.[213]

A burden-shifting approach presents a promising way to address lingering causation issues like these. Burden shifting can help courts manage inquiries that might otherwise involve open-ended explorations of ill-defined terrain. A burden-shifting approach to causation might be modeled after the rule of reason analysis itself.[214] It might also borrow from *Actos* and adopt, for example, a presumption of causation through the summary judgment stage.[215] As explained above, much of the heavy lifting for causation is in fact already accounted for through the inference that follows from a finding of an antitrust violation. This means that an independent causation analysis should likely be

211. *See supra* Part II.B.

212. Courts have recognized in a related context that if the theory of harm is that generic entry would promote competition, private plaintiffs must show that the generic manufacturer "was prepared to enter the market and intended to do so but for" the challenged conduct. *See* 1 HOVENKAMP ET AL., *supra* note 8, § 15.03[A], at 15-40 & n.147 (citing Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 806-07 (D.C. Cir. 2001)). Thus, when generic entry would happen following a successful approval by the FDA through the abbreviated process available to certain generic entrants—including those whose entry is delayed by a reverse payment settlement, *see supra* note 13—courts have required proof of "an expectation of success" in the FDA process. *See* 1 HOVENKAMP ET AL., *supra* note 8, § 15.03[A], at 15-41 & n.150 (collecting cases).

213. Such a theory was put forward in *Solodyn*, for example, but the court found it insufficient as a standalone barrier to causation at the summary judgment stage because a genuine dispute remained about whether the challenged agreement had "stifled competition." *See In re* Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-md-02503, 2018 WL 563144, at *23 (D. Mass. Jan. 25, 2018).

214. *See supra* note 3.

215. *See* United Food & Commercial Workers Local 1776 v. Takeda Am. Holdings (*In re* Actos End-Payor Antitrust Litig.), 848 F.3d 89, 101 (2d Cir. 2017).

an uphill battle for defendants unless they can point to a relatively simple causal flaw like earlier entry by a nonsettling generic manufacturer. Because potential causal flaws cannot all be readily identified and enumerated, the best approach here is likely to afford defendants some opportunity to rebut causation. The key is to eschew the narrow approach's expansion of the causation requirement into a vehicle for relitigating issues *Actavis* addressed because, properly analyzed, those issues are squarely accounted for under the violation prong.

Finally, in assessing these lingering causation concerns, courts should avoid replacing the narrow approach's missteps with new theories that similarly should have no role in the analysis. Two such red herrings most readily come to mind. First, a court may be tempted to deploy information about patent validity that was unknown (and unknowable) at the time of the settlement agreement. A postagreement final judgment of validity or invalidity, for example, might at first blush appear to dispose of the need for probabilistic reasoning. But the relevant antitrust question is what the settling parties agreed to based on their assessments of the probability of validity at the time of the agreement.[216] Of course, if such a final judgment on validity brings about other events that *do* affect the agreement's infliction of injury on consumers, those other developments should be taken into account directly. For example, if a nonsettling generic manufacturer successfully proves that a patent is invalid and enters the market in advance of the entry date contemplated under the illegal agreement, this actual entry may reduce—or even eliminate—consumer damages, as described above.[217] Second, a court might similarly think that there is compelling postagreement evidence that the generic parties to the agreement were unprepared to ever enter. But again, the relevant question is whether those parties were actually unprepared, as of the time of the agreement, to enter by the relevant baseline date. Once they have

216. *See* 1 HOVENKAMP ET AL., *supra* note 8, § 16.01[D], at 16-30; *see also supra* note 190. Even the courts that had adopted the "scope of the patent" test recognized the need to analyze how much delay was baked into an agreement from the parties' perspective at the time of the settlement. *See* 1 HOVENKAMP ET AL., *supra* note 8, § 16.01[D], at 16-30.

217. If, on the other hand, a postagreement challenge from a nonsettling generic manufacturer ends in a final judgment of *validity*, it is unlikely that this would produce a follow-on event affecting damages. It would be wrong to say that the validity finding itself changes the question whether the agreement caused consumer harm—this is precisely the error just described. That is why, in the case of a finding of *invalidity*, what is relevant is not the final judgment itself, but rather the subsequent entry it might trigger. Another way of putting this is that a final judgment either way on validity does not change the relevant baseline date (the expected entry date absent the agreement). What might be changed as a result of a final judgment of invalidity, however, is the degree to which generic entry is actually delayed beyond that baseline date.

secured a reverse payment, generic manufacturers have different incentives to prepare for market entry.[218]

Conclusion

The Supreme Court's 2013 decision in *Actavis* sent an important message to pharmaceutical companies: Reverse payment settlement agreements cannot categorically escape antitrust scrutiny. Data collected by the FTC suggests that *Actavis* has measurably reduced the number of potentially anticompetitive reverse payment settlement agreements.[219] But decisions from the First and Third Circuits threaten to reverse that trend by leaving *Actavis* with "no practical application except in suits by the government,"[220] reducing the deterrent effect private antitrust lawsuits are meant to provide.

The California Supreme Court and several federal district courts have already identified a better answer to the causation issue. This Note explains why that approach is the correct interpretation of *Actavis* and private antitrust law. Adopting the broader approach would bring much-needed clarity to this area of the law.

Uncertainty in this area should not be allowed to fester. Consider the consequences of not knowing whether litigation of patent validity is necessary to resolve a private reverse payment claim. As this Note explains, the narrow causation approach says such litigation is necessary, while the broader approach says it is not. The narrow approach's answer to this question brings with it a consequence neither the majority nor the dissent in *Actavis* proposed: Parties to an antitrust suit must litigate the merits of an already settled patent lawsuit. If this complex inquiry is superfluous (as this Note argues), that should be clear from the outset of litigation.

A handful of courts have staked out positions on causation, but the issue remains open in many others—including every federal court of appeals aside from the First and Third Circuits. The confusion and divide that has characterized decisions to date are telltale signs that Supreme Court review

218. *See, e.g.*, Am. Sales Co. v. AstraZeneca LP (*In re* Nexium (Esomeprazole) Antitrust Litig.), 842 F.3d 34, 45 (1st Cir. 2016) (mentioning the plaintiffs' theory that a generic party to the settlement agreement "slowed down its efforts toward [FDA approval] after settling with" the brand-name company).

219. *See* Bureau of Competition, FTC, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2015 1 (n.d.), https://perma.cc/9C35-ZK9G (reporting that in fiscal year 2015, "the number of settlements potentially involving pay for delay continue[d] to decrease significantly in the wake of the *Actavis* decision").

220. *See In re* Aggrenox Antitrust Litig., No. 3:14-md-2516 (SRU), 2015 WL 4459607, at *9 (D. Conn. July 21, 2015).

may ultimately be warranted. Yet no party has petitioned for certiorari on the causation question,[221] and the courts of appeals have declined invitations to exercise their powers of discretionary review here.[222] The result is that it is difficult to foresee how long it may be before a coherent, uniform approach to causation emerges in the courts. As more courts confront causation, the best path forward is to recognize that only the broader approach faithfully applies *Actavis* and private antitrust law.

221. In the relevant time period (post-*Actavis*), the key appellate decisions that squarely addressed a federal question about causation were *Wellbutrin* and *Nexium*. *See supra* Part II. According to searches of both the Supreme Court's online docket and Westlaw's database of petitions for certiorari, no petition was filed in either case.

222. The First and Third Circuits both denied petitions to review their decisions en banc, although the First Circuit panel did issue a new opinion addressing some of the arguments raised in the briefing requesting rehearing. *See* Am. Sales Co. v. AstraZeneca LP (*In re* Nexium (Esomeprazole) Antitrust Litig.), 845 F.3d 470 (1st Cir. 2017); Order Sur Petition for Rehearing, *supra* note 162. And a Second Circuit panel denied leave to appeal the *Aggrenox* district court's order directly implicating the causation question, which the district court had certified for interlocutory review. *See* Order, Barr Pharm. Inc. v. A.F. of L.-A.G.C. Bldgs. Trade Welfare Plan (*In re* Aggrenox Antitrust Litig.), No. 15-2416 (2d Cir. Sept. 16, 2015) (denying interlocutory review); *see also Aggrenox*, 2015 WL 4459607, at *8-11 (discussing the causation question raised by the court's earlier order and certifying that order for interlocutory review).