

PAY-FOR-DELAY: WHO DOES THE GENERIC INDUSTRY LOBBY REPRESENT?



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I. INTRODUCTION

The generic industry lobby, Association for Accessible Medicines (“AAM”), often represents the public interest. In the pharmaceutical industry, it challenges brand drug companies’ anticompetitive conduct. It fights for lower prices for consumers. And it has built up goodwill for its work in these areas.

But there is one glaring exception. Brand and generic companies often settle patent litigation. And sometimes they do so with the brand paying the generic to delay entry. To state the obvious, generics do well when brands pay them to stay off the market. But AAM’s fierce advocacy in favor of these “pay-for-delay” settlements has not received the attention it deserves.

This essay addresses this gap. It analyzes AAM’s advocacy against congressional pay-for-delay legislation and its briefs in two recent cases involving a Federal Trade Commission (“FTC”) challenge and California legislation. The essay concludes that in defending these blatantly anticompetitive deals, AAM does not represent the public interest.

II. DRAMA

One theme of AAM’s advocacy is drama. The group constantly warns that robust antitrust scrutiny will result in fewer generic drugs and higher prices. One setting involves AB 824, California’s legislation targeting pay-for-delay settlements. Lamenting that this legislation would result in calamitous consequences, AAM has sought to block it. In doing so, it has resorted to fear-mongering: AB 824 would “make it difficult, if not impossible” to settle patent litigation, “scuttle patent settlements now in the works and on the near-horizon,” “dissuade generic manufacturers” from “challenging patents,” and result in “fewer generic medicines on the market” and “higher prescription-drug prices.”²

AAM also has weighed in to try to overturn the FTC’s ruling against Impax. This ruling was the most thorough application of the Supreme Court’s 2013 landmark decision, *FTC v. Actavis*.³ And it offered a ringing bipartisan, unanimous (5-0) condemnation of pay-for-delay settlements. AAM nonetheless resorts to histrionics in its brief, claiming that the ruling will result in parties not having “the ability to settle patent cases,” which would “thwart . . .” generics’ “cost savings” because of “the need to litigate large patent portfolios all the way through trial.”⁴ Generics’ inability to “pursue the same number of patent challenges” would “ultimately mean . . . fewer [generic] and biosimilar filings, fewer patent challenges, and fewer

² Brief for Plaintiff-Appellant, *AAM v. Becerra*, at 47-48 (9th Cir. filed Jan. 30, 2020) (“California Brief”).

³ 570 U.S. 136 (2013).

⁴ Brief of the Association for Accessible Medicines as *Amicus Curiae* in Support of Respondent, *Impax Labs., Inc. v. FTC*, at 4 (5th Cir. filed Oct. 10, 2019) (“Impax brief”).

generics and biosimilars on the market.”⁵ The melodramatic argument is matched by an over-the-top style, with more than 50 bolded and italicized words in the *Impax* brief alone.

This is dangerous. Many associate AAM with the public interest. And its arguments do not sound frivolous on their face. So it is possible that courts and legislatures will consider this drama. The problem is that, as the remainder of this essay discusses, AAM’s arguments are foreclosed by the relevant caselaw and regulatory framework.

III. PATENT SCOPE

The centerpiece of the caselaw is *Actavis*, one of the most important antitrust cases in the past generation. In the decade before *Actavis*, lower courts had immunized anticompetitive patent settlements. These “reverse payment” settlements involve patent-holder brand firms paying potentially infringing generics to *delay* entry, which differs from the typical arrangement of alleged infringers paying patentees for licenses to *enter* the market. Courts had upheld these settlements (also known as “pay for delay”) on several grounds: that they fell within the “scope of the patent,” benefited from a presumption of patent validity, were the “natural by-product” of industry legislation, and were supported by the public policy in favor of settlement.⁶ In rejecting these arguments, *Actavis*’s importance cannot be overstated. The Court held that reverse-payment settlements have the potential for “significant adverse effects on competition” and could “violate the antitrust laws.”⁷

Given this roadblock to its position, AAM ignores, downplays, or mischaracterizes *Actavis* whenever it can. First, AAM takes direct aim at *Actavis*’s most fundamental underpinning, which focused on the relationship between patent and antitrust law. Courts before *Actavis* had upheld reverse-payment settlements as a type of activity falling within the scope of the patent. They reasoned that payment did not “unlawfully extend the reach of the patent” since the patent holder could exclude competition based on the patent itself.⁸ In other words, while the patent was still in force, antitrust had no role to play.

The Court in *Actavis* rejected this test. It reviewed the caselaw, tracing antitrust’s robust role in evaluating patent arrangements back to the mid-20th century. The Court found it “incongruous” to “determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well.” It made clear that “patent and antitrust policies are both relevant in determining the ‘scope of the patent monopoly’—and consequently antitrust law immunity—that is conferred by a patent.” And it recognized that reverse-payment settlements had the “potential for genuine adverse effects on competition” since “payment in return for staying out of the market. . . keeps prices at patentee-set levels.”⁹

In direct contravention of this ruling, AAM seeks to resuscitate the overturned scope-of-the-patent test. It calls “entry before patent expiration” a “procompetitive result not frequently achieved in litigation.”¹⁰ And in the *Impax* case, it claims that the settlement with Endo allowed *Impax* to enter “*ten years* earlier than otherwise possible” and “eight months before expiration of Endo’s original patent monopoly.”¹¹

AAM’s position is not consistent with *Actavis*, which made clear that in applying antitrust law, courts cannot simply assume that the patent is valid and infringed. Just because a generic can enter before the patent expires does not mean that a settlement automatically is procompetitive. After all, that patent might not have been valid, and in such a case, the generic’s delaying entry because of payment improperly extends monopoly power.

5 *Id.* at 12.

6 See Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 60-67 (2009) (describing cases).

7 570 U.S. at 141, 148.

8 *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006); see also *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

9 570 U.S. at 147-51, 154.

10 *Impax* brief, at 12.

11 *Id.* at 2 (emphasis in original, bold omitted), 26.

IV. PAYMENT

Actavis was a foundational ruling not only in cementing antitrust's position but also in emphasizing the key role played by payment, which marks the dividing line between anticompetitive and procompetitive settlements. Drug companies settle cases all the time without payment. Such "patent-term split agreements" involve brands and generics dividing the remaining patent term by selecting a time for generic entry based on the patent's strength. The Court in *Actavis* thus found that settlement allowing entry before patent expiration could "bring about competition . . . to the consumer's benefit."¹²

The problem with payment is that the brand firm obtains more exclusivity than the patent would warrant. In other words, the brand keeps the generic off the market based on not the strength of its patent but the size of its payment. It goes without saying that potential competitors cannot divide markets through payments from one to another not to compete. That is illegal.¹³ And that is what happens when a brand pays a generic to delay entry.

Payment not only distinguishes between anticompetitive and procompetitive settlements but also allows courts to avoid wading into the merits of the patent litigation to decide the antitrust case.¹⁴ The Supreme Court found it "feasible" for a court to evaluate the antitrust effects of settlements because "it is normally not necessary to litigate patent validity to answer the antitrust question." The reason is that "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." In fact, "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself."¹⁵

Payment's crucial role — and the relative infrequency today of settlements with payment — may help explain why AAM resorts to drama. For example, in arguing against AB 824, California's pay-for-delay legislation, the group relies on a syllogism: (1) generic entry lowers price; (2) settlement facilitates generic entry; (3) AB 824 bars settlements; (4) AB 824 increases price. The syllogism flows easily. And it paints a scary story. But it is not accurate. For there is a fundamental problem.

And that problem lies at the third step: that AB 824 targets all settlements. Such an assertion is completely unsupported, as AB 824 targets only the minor subset of settlements involving payment. Throughout its brief seeking to block the legislation, not one of AAM's numerous references to AB 824's effects on settlements even hints at payment. But as discussed in this section, *Actavis* drew a critical distinction between settlements with and without payment. In ignoring this holding, AAM neglects a centerpiece of *Actavis* and subsequent caselaw.

V. PREEMPTION

In its advocacy, AAM not only seeks to undercut *Actavis* but also, as discussed above, endeavors to block California's reasonable legislation targeting pay-for-delay settlements. In particular, it claims that AB 824 is preempted by the Hatch Waxman Act (Congress's landmark statute balancing competition and innovation in the pharmaceutical industry) and by patent law.

First, AAM claims that the legislation is "fundamentally at loggerheads with the Hatch-Waxman Act," as it would make it "impossible" to settle cases, "dissuade" patent challenges, and result in "fewer generic[s]" and "higher . . . prices."¹⁶ Even though the Hatch Waxman Act has increased generic competition, reverse-payment settlements have undermined the legislature's goals. A central element of this subversion has been the 180-day exclusivity period that Congress created to encourage generics to be the first to certify that brand patents are invalid or not infringed.¹⁷ This bounty, however, has been twisted from an incentive for generics to challenge and *enter* to a mechanism for preventing challenges

¹² 570 U.S. at 154.

¹³ See, e.g. *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 48 (1990).

¹⁴ *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1315 (11th Cir. 2012) (referring to "turducken" approach of "deciding a patent case within an antitrust case about the settlement of the patent case").

¹⁵ 570 U.S. at 157-58.

¹⁶ California Brief, at 47-48.

¹⁷ 21 U.S.C. § 355(j)(2)(A)(vii).

and *delaying* entry. In fact, by settling with the first challenger, the brand firm can significantly delay other generics' entrance into the market.¹⁸

Such payment for delayed entry contravenes the competition goals at the heart of the Hatch Waxman Act. The drafters have said so themselves. Representative Waxman explained that reverse-payment agreements “turn . . . the . . . legislation on [its] head.”¹⁹ Waxman emphasized that the purpose of the legislation was to promote generic competition, not to allow generics “to exact a portion of a brand-name manufacturer’s monopoly profits in return for withholding entry into the market.”²⁰ Senator Hatch similarly found such agreements “appalling.” And his assessment mirrored that of Waxman in making clear that “[w]e did not wish to encourage situations where payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition.”²¹

AAM also claims that AB 824 “upsets the balance Congress struck in federal patent law and the Supreme Court went out of its way to protect in *Actavis*.”²² But this contention is incorrect on at least four grounds, based on antitrust preeminence, patent irrelevance, patent challenges, and exclusive licenses.

First, AAM’s claim is belied by *Actavis*, which made clear that antitrust plays a crucial role in the analysis of patent settlements. As discussed above, *Actavis* rejected the absolutist scope-of-the-patent approach, forging a careful equilibrium between patent and antitrust that foils any attempt to extricate antitrust from the analysis.

A second reason why patent law does not preempt AB 824, again as discussed above, is the irrelevance of the patent’s merits. *Actavis*’s emphasis on payment allows courts to avoid wading into the merits of the patent litigation to decide the antitrust case.

Third, the importance of challenging invalid patents also supports AB 824. The Supreme Court made clear that the problem with payment is that it blocks the “risk of competition” on invalid patents, which “constitutes the relevant anticompetitive harm.”²³ The Court also recognized the crucial “patent-related policy” of “eliminating unwarranted patent grants so the public will not ‘continually be required to pay tribute to would-be monopolists without need or justification.’”²⁴

Fourth, AAM contends that “whereas the Patent Act expressly confers the right to grant exclusive licenses, AB 824 deems all ‘exclusive license[s]’ to be presumptively anticompetitive.”²⁵ But in *Actavis*, the Court went back decades to trace its history of finding that patent-based arrangements — *allowed under patent law* — violated antitrust law.²⁶ Since *Actavis*, courts have recognized that exclusive licenses are not immune from antitrust scrutiny, with the Third Circuit, for example, explaining that the exclusive license the defendant tried to defend “is not in fact a patentee’s right to grant licenses, exclusive or otherwise,” but “[i]nstead . . . is a right to use valuable licensing in such a way to induce a patent challenger’s delay,” conduct that *Actavis* “rejected.”²⁷

18 See HOVENKAMP ET AL., IP AND ANTITRUST, § 16.01[A], at 16-10 to 16-11 (2018 Supp.).

19 Motion & Brief of Representative Henry A. Waxman as *Amicus Curiae* in Support of Petitioner at *1, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2462026.

20 *Id.*

21 148 CONG. REC. S7566 (daily ed. July 30, 2002).

22 California Brief, at 39.

23 570 U.S. at 157.

24 *Id.* at 151 (citing *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)).

25 California Brief, at 5.

26 570 U.S. at 148-50.

27 *King Drug v. SmithKline Beecham Corp.*, 791 F.3d 388, 407 (3d Cir. 2015).

VI. ANTITRUST FRAMEWORK

AAM also seeks to impose its unjustified position on the type of antitrust analysis courts are to perform after *Actavis*. In offering its position, it ignores *Actavis*, citing general antitrust cases having little to do with the framework courts have applied in pay-for-delay cases in the past several years.

Although *Actavis* adopted a type of rule-of-reason analysis, this was not the “typical exhaustive consideration of a restraint’s anticompetitive and procompetitive effects,” but instead was a “more abbreviated analysis.”²⁸

The Court adopted several shortcuts favoring plaintiffs. First, it found that the “size of the payment” serves as “a strong indicator of power,”²⁹ which makes sense since “[a] producer in a highly competitive market would not pay anything to keep a rival out because price-cost margins are already low and keeping one firm out would not improve that situation.”³⁰ And second, the Court found that a large and unjustified payment has the “potential for genuine adverse effects on competition” because the payment “in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed.”³¹

The Court further streamlined the analysis by accepting only two of defendants’ proffered justifications: (1) payments “amount[ing] to no more than a rough approximation of the litigation expenses saved through the settlement” and (2) “compensation for other services that the generic has promised to perform.”³² As a result, the settling parties are no longer able to offer reasons based on reducing risk or allowing entry before the end of the patent term. The Court confirmed this abbreviated analysis in directing lower courts to “avoid . . . consideration of every possible fact or theory irrespective of the minimal light it may shed on . . . the presence of significant unjustified anticompetitive consequences.”³³ In short, “the Court appears to have all but in name adopted the presumptive illegality approach it purported to reject.”³⁴

The Court’s recognition of only two justifications, and its rejection of the scope-of-the-patent test, precludes AAM’s attempt to rewrite the rule of reason in this setting by (1) raising the bar for plaintiffs by cherry-picking (and *emphasizing* in bold and italics) individual words from unrelated antitrust cases, (2) offering as a procompetitive benefit entry before the end of the patent term, and (3) requiring balancing in every rule-of-reason case.³⁵ Such efforts would undermine *Actavis* and immunize pay-for-delay settlements.

AAM also urges courts to evaluate agreements “as a whole,” lamenting the FTC’s “cramped reading” in *Impax* that required Impax to “directly ‘link’ the proffered benefits to the purported payment.”³⁶ And it criticizes the “piecemeal analysis of an agreement’s individual provisions lest [courts] miss the forest for the trees.”³⁷ But these pleas fly in the face of *Actavis*, as the Court made clear that a defendant must justify “the presence of the *challenged term* and show . . . the lawfulness of *that term* under the rule of reason.”³⁸ As recognized by other Supreme Court rulings and the leading antitrust treatise, such a position is not controversial.³⁹

28 Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7, 30 (2014).

29 570 U.S. at 157.

30 Aaron Edlin et al., *Activating Actavis*, 28 ANTITRUST 16, 17 (2013).

31 570 U.S. at 153-54.

32 *Id.* at 156.

33 *Id.* at 159-60.

34 Thomas F. Cotter, *FTC v. Actavis, Inc.: When is the Rule of Reason Not the Rule of Reason?*, 15 MINN. J. L., SCI. & TECH. 41, 43 (2014).

35 *Impax* brief, at 14-15, 17, 19.

36 *Id.* at 19-20.

37 *Id.* at 20.

38 *Actavis*, 570 U.S. at 156 (emphases added).

39 See, e.g., *NCAA v. Board of Regents*, 468 U.S. 85, 117 (1984) (defendants must justify the “specific restraints on football telecasts that are challenged in this case”); VII PHILLIP E. AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION* ¶ 1505a, at 432 (4th ed. 2013).

The FTC thus was on solid ground in its *Impax* ruling when, in considering procompetitive justifications, it “look[ed] at the specific restraint, not the agreement as a whole.”⁴⁰ The agency found that Impax “never attempt[ed]” to show that the provisions that involved payment “*themselves* protected Impax from the threat of patent infringement suits.”⁴¹

As the Commission recognized, a “contrary rule would allow parties to skirt liability for anticompetitive behavior by inserting unrelated provisions into their contracts and claiming that those provisions benefited competition.”⁴² Remarkably, AAM’s proposed approach would be more deferential than the scope-of-the-patent test by allowing settlements that blocked generic entry even *after* the patent term as long as the settling parties could point to other provisions, like a license to unrelated patents. And in fact, if the Supreme Court had adopted AAM’s framework, *Actavis* itself would have come out the other way since the brand’s payment would have been downplayed in comparison to the generic’s entry 65 months before the end of the patent term.⁴³

AAM also ignores the possibility of at-risk entry. As discussed above, in the *Impax* case, AAM claimed that the settlement with Endo allowed Impax to enter “*ten years* earlier than otherwise possible” and “eight months before expiration of Endo’s original patent monopoly.”⁴⁴ This, however, ignores the possibility of generics entering the market “at risk,” before a court has ruled that the patent is invalid or not infringed. After the FDA approved Impax’s generic application in June 2010, the company posed a “real threat of competition,” with its senior management “consider[ing] launching ‘at risk’” and “tak[ing] a number of steps to prepare,” including forecasting a 2010 launch, presenting such a launch to the board of directors, and obtaining approvals and manufacturing products.⁴⁵ In short, the FTC met its burden of showing the plausibility of an at-risk launch, which would have introduced generic competition before the patent litigation ended.

AAM also claims that the Commission “removed its burden to prove that a real, lesser-restrictive settlement option was viable,” instead “fashion[ing] a wholly theoretical benchmark” and (as discussed below, taking great liberties with the opinion) “flipp[ing] the burden to Impax to demonstrate that a less restrictive settlement was impossible.”⁴⁶ Real-world evidence, however, shows that brands and generics are able to settle without payment. In fact, they are overwhelmingly able to do so.

For the past 15 years, the FTC has reviewed every settlement of drug patent litigation and published annual reports detailing the number of settlements, including the number involving payment and delayed entry. In a nutshell, when the courts are applying robust antitrust scrutiny, the number of pay-for-delay settlements falls, as it did between 2000 and 2004, when 0 out of 20 settlements involved payment, and as it has since *Actavis*, when the number of pay-for-delay settlements fell from 33 (out of 140 total settlements) in 2012 to 1 (out of 232) settlements in 2016.⁴⁷ In contrast, when the courts abandon antitrust scrutiny, as they did between 2005 and 2012, the number of pay-for-delay settlements skyrockets. The Court in *Actavis* thus was on solid empirical ground when it explained that the parties could settle by allowing the generic “to enter . . . prior to the patent’s expiration, without the patentee paying the challenger to stay out prior to that point.”⁴⁸

Despite *Actavis* and this real-world evidence, the FTC still gave Impax the chance to show that this could have been the unique case in which payment was needed for a procompetitive settlement. But Impax’s lead settlement negotiator conceded that he did not recall “(1) whether Impax ever ‘tried to get a date earlier than January of 2013’; (2) how Endo reacted to the prospect of an earlier date; or (3) whether Endo ever told Impax that it would ‘not settle the litigation’ with an entry date before 2013.”⁴⁹

40 *In the Matter of Impax Labs., Inc.*, at 32 (FTC Dkt. No. 9373, March 28, 2019) (“FTC Opinion”).

41 *Id.* at 37 (emphasis in original).

42 *Id.* at 36 n.40.

43 570 U.S. at 145.

44 *Impax* brief, at 2 (emphasis in original, bold omitted), 26.

45 *FTC Opinion*, at 24.

46 *Id.* at 8 (italics and bold omitted).

47 FTC Bureau of Competition, *Summary of Agreements Filed in FY 2004*, <https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/050107medicareactrpt.pdf>; FTC Bureau of Competition, *Overview of Agreements Filed in FY 2016*, <https://www.ftc.gov/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-fy2016> (14 additional settlements contain “possible compensation”).

48 570 U.S. at 158.

49 *FTC Opinion*, at 41 n.43.

In short, in advocating for an unsupported deferential approach, seeking to analyze the agreement as a whole, ignoring plausible at-risk entry, and neglecting the less restrictive alternative of settlement without payment, AAM offers an antitrust analysis having little to do with *Actavis* or subsequent caselaw.

VII. FLAWS

In addition to all of these substantive problems with AAM's positions, the group's advocacy is based on internal contradictions and misleading assertions.

First, AAM contradicts itself. As discussed throughout this essay, in litigation, AAM ominously warns that robust antitrust analysis will preclude future settlements, while suggesting that *Actavis* provided a deferential Rule-of-Reason antitrust analysis. But in seeking to block pay-for-delay legislation, AAM argues the *exact opposite*. Far from predicting the end of settlements, it concedes that "the vast majority" of settlements do not involve payment.⁵⁰ And unlike the deferential antitrust analysis it finds in *Actavis* for litigation purposes, it urges Congress not to pass legislation because "the Supreme Court prohibited 'pay-for-delay' deals."⁵¹

Second, AAM misleads. In advocating against legislation, the group claims that *Actavis* "recognize[d] the value of settlements and the patent litigation problem."⁵² But AAM neglects to mention *Actavis*'s next sentence, which made clear that "this patent-related factor should not determine the result" and that "the FTC should have been given the opportunity to prove its antitrust claim."⁵³

AAM also deceives about the FTC's ruling in *Impax*. AAM twists *the company's* claim that "a no-payment settlement was impossible"⁵⁴ into an FTC-imposed burden on *Impax* "to demonstrate that a less restrictive settlement was *impossible*."⁵⁵ And it replaces accuracy with drama in claiming that the FTC "gerrymandered" and "attempt[ed] to rig" the analysis to "a *fait accompli*."⁵⁶

Another example of misdirection is AAM's attempt to downplay *Actavis*. AAM claims that this landmark decision was confined to the "limited circumstances" presented by "large and unjustified" payments.⁵⁷ But given the Supreme Court's rejection of the scope-of-the-patent test and robust recognition of antitrust enforcement, that is like saying the landmark case of *United States v. Socony-Vacuum Oil* held that price fixing between rivals is *per se* illegal only in the "limited circumstances" in which there is an agreement.⁵⁸

AAM's reliance on self-contradiction and deception speaks volumes.

50 AAM, *Check the Facts on "Pay-for-Delay" Legislation*, <https://accessiblemeds.org/sites/default/files/2019-05/AAM-Patent-Settlement-Fact-Sheet.pdf> (last visited Mar. 21, 2020).

51 *Id.*

52 *Id.*

53 570 U.S. at 153.

54 FTC Opinion, at 41.

55 *Impax* brief, at 9 (bold and italics in original); see also *id.* at 25 (same).

56 *Id.* at 9.

57 California Brief, at 40; see also *id.* at 12 (*Actavis* "sharply restricted the scope of antitrust review of patent settlements").

58 310 U.S. 150 (1940).

VIII. CONCLUSION

For most pharmaceutical conduct, AAM represents the public interest. On “product hopping” (switching from one version of a drug to a trivially-different version), frivolous citizen petitions filed with the U.S. Food and Drug Administration to delay entry, and the denial of samples that generics need to enter the market, AAM challenges unwarranted patent monopolies and encourages market entry to lower prices and benefit consumers.⁵⁹

Pay-for-delay settlements are different. As this essay has shown, AAM has misrepresented the law and engaged in misleading advocacy to protect generic companies that benefit from these anticompetitive agreements. Pay-for-delay settlements cost consumers billions of dollars and force patients to forgo needed medicines. Courts and Congress should keep in mind who AAM really represents when it vociferously argues against antitrust enforcement of anticompetitive pay-for-delay settlements.

⁵⁹ See *Statement by Michael A. Carrier to Senate Judiciary Committee on “Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition,”* May 7, 2019, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3442650.

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