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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

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| ASSOCIATION FOR ACCESSIBLE MEDICINES,<br><br>Plaintiff,<br><br>v.<br><br>XAVIER BECERRA, in his official capacity as Attorney General of the State of California,<br><br>Defendant. | Case No. 2:19-CV-02281-TLN-DB<br><br>**BRIEF *AMICUS CURIAE* OF THE AMERICAN ANTITRUST INSTITUTE IN SUPPORT OF DEFENDANT** |

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## INTEREST OF *AMICUS CURIAE*

The American Antitrust Institute ("AAI") is an independent nonprofit organization devoted to promoting competition that protects consumers, businesses, and society. It serves the public through research, education, and advocacy on the benefits of competition and the use of antitrust enforcement as a vital component of national and international competition policy. AAI enjoys the input of an Advisory Board that consists of over 130 prominent antitrust lawyers, law professors, economists, and business leaders. *See* http://www.antitrustinstitute.org.[1]

AAI submits this brief because the consumer harm caused by payments for delayed generic entry into pharmaceutical markets supports implementation and enforcement of AB 824.

## INTRODUCTION AND SUMMARY OF ARGUMENT

Americans, on average, pay the highest prescription drug prices in the world, by far.[2] By enacting AB 824, California has followed the U.S. Supreme Court's lead in taking the next step to help address this problem by eradicating cost-raising conduct that violates the antitrust laws. AB 824 does this by creating a rebuttable presumption of illegality when branded pharmaceutical companies ("brands") settle patent-infringement lawsuits by paying generic pharmaceutical companies ("generics") to delay launching generic drugs, which excludes generic competition from pharmaceutical markets. These exclusion-payment settlements are one of the most harmful forms of anticompetitive business behavior in today's economy. They are estimated to cost consumers $3.5 billion annually,[3] and they lead patients to miss dosages of needed medications by splitting pills in half or not take them at all.

Exclusion payments today take myriad forms, including above-market-value business

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[1] All parties consent to the filing of this proposed *amicus* brief. No counsel for a party has authored this proposed brief in whole or in part, and no party, party's counsel, or any other person—other than proposed *amicus curiae* or its counsel—has contributed money that was intended to fund preparing or submitting this brief. Individual views of members of AAI's Board of Directors or its Advisory Board may differ from AAI's positions.

[2] Peter Olson & Louise Sheiner, *The Hutchins Center Explains: Prescription Drug Spending*, Brookings.edu (Apr. 26, 2018).

[3] FTC Staff Study, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Jan. 2010); *see also* Congressional Budget Office, *Preliminary Estimate for S. 2019, the Preserve Access to Affordable Generics Act* (Dec. 20, 2015) (estimating that federal legislation to adopt presumptive illegality framework would reduce federal spending by $2.4 billion over 10 years).

deals like those at issue in *FTC v. Actavis*, 570 U.S. 136 (2013), and numerous other types of transfers of substantial economic value. The Court in *Actavis* found that a large and unjustified transfer of consideration from a brand to a generic, in exchange for the latter's delayed entry, could have "significant anticompetitive effects" and violate the federal antitrust laws. *Id.* at 158. This watershed ruling definitively established that exclusion-payment settlements are not immune from antitrust scrutiny. Although the *Actavis* Court declined to formally adopt a quick-look standard or presumption of illegality regarding such settlements—holding instead that they should be evaluated under the rule of reason[4]—it left the door open for other institutions to go further, even under federal antitrust law, in combatting this pernicious practice. *Actavis*, 570 U.S. at 159-60.

For more than a century, courts and legislators have sought to balance the goals of antitrust law, which promotes competition, and patent law, which gives inventors a right to exclude others from making, using or selling a patented product, in the service of a dynamic economy. The Hatch-Waxman Act is Congress's framework for striking this balance in the pharmaceutical industry. The Act offers a 180-day period of exclusivity to the first generic to challenge a brand firm's patent as invalid or not infringed. The exclusivity award is intended to encourage generic manufacturers to challenge weak patents and enter the market earlier with cheaper drugs. But this carefully crafted scheme has been upended by brands' payments of millions of dollars to generics to abandon their patent challenges and delay entering the market. These exclusion payments, also called "reverse payments" because the plaintiff patentee settles by paying the alleged infringer (rather than vice versa), violate basic antitrust principles and deprive consumers of low-cost generic drugs.

Antitrust law has long forbidden agreements among horizontal competitors to allocate markets, which is the practical result when brands pay generics to drop challenges to weak patents and delay entering the market. But exclusion-payment settlements also fly in the face of

[4] The court, however, did not require the "typical exhaustive consideration of a restraint's anticompetitive and procompetitive effects," instead anticipating a "more abbreviated analysis." Michael A. Carrier, *Payment After Actavis*, 100 Iowa L. Rev. 7, 30 (2014).

patent law. While patent law properly limits competition in some respects, it does so only subject to the limits set forth in the Patent Act. And courts have recognized that patent policy not only permits legal challenges to weak patents but affirmatively encourages them. Indeed, the patent grant itself provides only a presumption of validity.

The patents at the heart of exclusion-payment agreements often cause concern. They frequently cover not the drug's active ingredient, but narrower aspects like the formulation or method of use that are less innovative and hold more potential for anticompetitive mischief. They are often added late in a drug's life, after the patent on the active ingredient has expired, and they tend to fare poorly when their validity is ultimately litigated. *See* Henry Grabowski et al., *Pharmaceutical Patent Challenges: Company Strategies and Litigation Outcomes*, 3 Am. J. Health Econ. 33, 53 (2017) (brands win only 19% of method-of-use challenges and 3% of formulation challenges). When a patentee pays a generic to drop its validity challenge, this suggests there is good reason for both parties to believe, at the time of settlement, that the patent in question is invalid or not infringed.

AAI has long supported an antitrust framework that treats exclusion-payment settlements as presumptively unlawful based on a quick-look analysis. This test recognizes the potentially severe anticompetitive effects of exclusion payments while also allowing the settling parties to offer justifications for their facially anticompetitive agreement. AB 824 adopts a presumptive-illegality approach, while providing multiple means for the parties to an exclusion-payment settlement to rebut the presumption.

## ARGUMENT

### I. THE HATCH-WAXMAN ACT WAS INTENDED AND DESIGNED TO ENCOURAGE PATENT CHALLENGES AND EARLY GENERIC ENTRY

Drug patent settlements involving generics must be considered in the context of the Hatch-Waxman Act, which Congress enacted in 1984 to increase generic competition and foster innovation in the pharmaceutical industry. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). Before the Act, a generic firm was required to engage in lengthy and expensive clinical trials that largely replicated the trials

conducted by the brand and that the generic could not begin during the patent term. As a result, roughly 150 drugs had no generic equivalent even after the brands' patent terms had expired. H.R. Rep. No. 98-857, pt. 1, at 17 (1984).

The Hatch-Waxman Act created a new legal framework to facilitate expedited approval of generic drugs by the U.S. Food and Drug Administration ("FDA"), allowing generics to enter the market during the patent term under certain conditions. A central element is the "paragraph IV certification," in which a generic certifies that the brand's patents are "invalid or will not be infringed" by the generic. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). To encourage market entry via these challenges, the drafters created a 180-day period of marketing exclusivity reserved for the first generic to make a paragraph IV filing. 21 U.S.C. § 355(j)(5)(B)(iv). The FDA cannot approve any other generic application for the same drug during this 180-day period. *Actavis* explained that, because no other generic version is on the market, the exclusivity period "has proved valuable" and "indeed … can be worth several hundred million dollars" to the generic. 570 U.S. at 155.

Over the last 20 years, the form of payment used in anticompetitive exclusion-payment settlements has evolved dramatically. Early agreements involved naked cash payments from the brand to the generic, as in *In re Cipro Cases I & II*, 348 P.3d 845, 852 (Cal. 2015) ($398 million). But more recent settlements are more complicated, with the brand overpaying for services provided by the generic (such as supplying materials or promoting products) or the generic underpaying for the brand's product line or service offerings. *See, e.g.*, C. Scott Hemphill, *The Aggregate Approach to Antitrust: Using New Data and Agency Rules to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 663-68 (2009). In another variation, the brand pays the first-filing generic by agreeing not to launch its own "authorized generic" to compete against the generic during the generic's 180-day exclusivity period. A brand's promise not to introduce an authorized generic during the 180-day exclusivity period is enormously valuable to the first-filing generic. *See, e.g., King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015) (plausibly "worth millions of dollars, if not hundreds of millions of dollars" (citation omitted)), *cert. denied*, 137 S. Ct. 446 (2016).

That generics take such complex measures to camouflage exclusion payments speaks to the enormity not only of the profits they reap for generics but also the anticompetitive injury they cause consumers.

## II. EXCLUSION PAYMENTS ARE FACIALLY ANTICOMPETITIVE

Of all the types of business activity subject to the antitrust laws, agreements by which competitors divide markets are the most dangerous.[5] Even price fixing (unlawful as it is) allows the parties to compete on dimensions other than price, such as quality or service. Market division restricts *all* competition between parties on *all* grounds.

Brand firms enter into exclusion-payment settlements with generics whereby the generic firm (1) drops its patent challenges and (2) agrees to delay entering the market. In return, the brand pays the generic millions—sometimes tens or hundreds of millions—of dollars, in cash or in kind. These payments are profitable to the settling parties precisely because they eliminate actual or potential competition. Because the brand firm makes more by keeping the generic out of the market than the two parties would receive by competing, the parties have a mutual incentive to cede the market to the brand firm and split the monopoly profits. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391, 408 (2003). The brand then can use a portion of this additional profit from delayed competition to pay the generic.

Exclusion payments are fairly characterized as the brand's purchase of the generic's agreement to cease or delay its efforts to enter the market and compete against the patented drug. An agreement concerning the generic entry date, without any cash payment, will normally reflect the odds of the parties' success in patent litigation: the more likely the patentee is to win the case, the more it can rely on the patent itself to exclude competition. 1 Herbert Hovenkamp et al., *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 15.3, at 15-45 (2d ed. Supp. 2010). But supplementing an entry-date agreement with a payment to the

[5] Courts have long recognized the severe harms presented by market division, regardless of whether the competitors allocate the entire market to one of them or allocate part of the market to each of them. *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49 (1990) (per curiam) ("Such agreements are anticompetitive regardless of whether the parties split a market within which both do business or whether they merely reserve one market for one and another for the other."); *see also United States v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972).

generic to stay out of the market changes that calculus, because the brand is likely to gain additional exclusivity beyond what the entry-date agreement provides. The quid pro quo for the payment would appear to be the generic's agreement to stay out of the market beyond the expected entry date that would result from litigation.

Settlements by which brands pay generics not to enter the market pose dangers analogous to territorial market allocation. Instead of allocating geographic space, they allocate time, blocking *all* competition for a drug for a period of time.

It is plain that a naked agreement by a patent holder to pay a competitor or potential competitor not to challenge its patent is per se illegal. *Palmer*, 498 U.S. at 48. The fact that such an agreement is contained in a settlement of patent litigation may suggest that procompetitive justifications could be entertained, but it is hardly a defense in and of itself. On the contrary, if a term of a patent settlement unreasonably restrains competition, it is exactly the type of conduct the antitrust laws are designed to prevent. *See, e.g.*, *United States v. Singer Mfg. Co.*, 374 U.S. 174, 194-95 (1963) (striking down a patent settlement excluding foreign competitors from the U.S. market). The Court in *Actavis* was unambiguous (indeed, redundant) in instructing that eliminating the risk that a patent would be found invalid or not infringed—the risk that competition would break out—is anticompetitive, *not* procompetitive. The payment "likely seeks to prevent the risk of competition," which "constitutes the relevant anticompetitive harm." *Actavis*, 570 U.S. at 157.[6]

With an exclusion payment, the brand firm buys assurance that its patent will not be invalidated—something that patent law alone does not give and the Hatch-Waxman Act did not contemplate.

## III. EXCLUSION-PAYMENT SETTLEMENTS ARE NOT IN THE PUBLIC INTEREST

Pharmaceutical companies argue that exclusion-payment settlements are necessary to

[6] The Court makes this point multiple times. *See* 570 U.S. at 152 (the antitrust violation occurs when "A, the plaintiff, pays money to defendant B purely so B will give up the patent fight"); *id.* at 156 (the antitrust concern is "that a patentee is using its monopoly profits to *avoid the risk* of patent invalidation or a finding of noninfringement" (emphasis added)); *id.* at 151 (rejecting dissent's approach that would permit "a patent holder [] to simply 'pa[y] a competitor to respect its patent' and quit its invalidity or noninfringement claim . . ." (citation omitted)).

settle disputes. In fact, however, this particular form of settlement is unnecessary and undesirable.

### A. Not All Settlements Are Desirable

The general preference for settlement over litigation must be tempered when settlements have important adverse effects on third parties; in the language of economics, there is no good reason to encourage settlements that impose significant negative externalities. *See* Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 Harv. L. Rev. 1813, 1867-73 (1984). The *Actavis* Court criticized excessive deference to the public policy in favor of encouraging settlements. Such excessive deference played a role in federal appellate courts' insufficient scrutiny of exclusion-payment settlements under federal law in the decade before *Actavis*. Indeed, the *Actavis* Court exhaustively detailed why the policy in favor of encouraging settlements is not commanding enough to outweigh all the other policy considerations favoring antitrust scrutiny of exclusion-payment settlements. *Actavis*, 570 U.S. at 158.

Drug patent settlements with exclusion payments are not typical settlements. They are agreements that dispose of the validity and infringement challenges central to the Hatch-Waxman scheme. *Id*. at 147-48 ("That form of settlement is unusual. And, . . . there is reason for concern that settlements taking this form tend to have significant adverse effects on competition."). Litigation under the Hatch-Waxman framework "put[s] the patent's validity at issue, as well as its actual preclusive scope. The parties' settlement end[s] that litigation." *Id*. at 147. Any general preference in the law for settlement was displaced—or at least significantly weakened—by the Act's specific framework.

A 180-day period of exclusivity for the first generic to successfully challenge a patent only makes sense in the context of encouraging challenges to patents that are likely weak. The period applies only to generics that seek to enter before the end of the patent term. It does not apply to challenges that target expired patents or delay approval until the end of the patent term. A successful patent challenge provides valuable (and in the case of medicines, necessary) benefits to third parties, including consumers and anyone who seeks to practice the patented technology. It also can accelerate competition from subsequent generics that enter after the conclusion of the

180-day exclusivity period.

In addition, the 180-day "bounty" itself demonstrates the unique nature of these agreements. General patent settlements do not prevent other competitors from entering the market. In cases outside the Hatch-Waxman context, even if the settling defendant agrees not to challenge the patent, others are free to enter. The Hatch-Waxman context is different. Alone among all categories of patent settlements, the Hatch-Waxman Act blocks alleged infringers from entering the market until the first paragraph-IV filer enjoys 180 days of marketing exclusivity. This period does not even begin until the first filer enters the market, potentially years down the road.[7] "These features together mean that a reverse payment settlement with the first filer . . . 'removes from consideration the most motivated challenger, and the one closest to introducing competition.'" *Actavis*, 570 U.S. at 155 (citing C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1586 (2006)). Indeed, the Supreme Court has noted that it may be this 180-day exclusivity period, unique to the Hatch-Waxman context, that "does much to explain why in this context, but not others, the patentee's ordinary incentives to resist paying off challengers (*i.e.*, the fear of provoking myriad other challengers) appear to be more frequently overcome." 12 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 2046, at 341 (3d ed. 2012) (noting that these provisions, "no doubt unintentionally, have created special incentives for collusion"); *Actavis*, 570 U.S. at 156.

An Act intended to increase generic entry should not be perverted into a tool to bar that entry by the mere invocation of a general policy favoring settlement. This is particularly true for an Act intended to *discourage* "deals between brand and generic companies to delay competition." *Actavis*, 570 U.S. at 152-53 (citing 148 Cong. Rec. 14437 (2002) (remarks of Sen. Hatch)).

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[7] The Medicare Modernization Act of 2003 created various "use it or lose it" provisions that can result in generics forfeiting their 180-day exclusivity period. But a careful reading of the statute shows that these provisions do not trigger forfeiture as quickly as might be assumed. Simplifying greatly, the statute provides that the first filer loses exclusivity if it fails to market the drug by the later of (1) 75 days after FDA approval or (2) 75 days after an appellate court decision finding invalidity or non-infringement. 21 U.S.C. § 355(j)(5)(D)(i). Appellate court decisions typically will not occur until years in the future.

**B. Exclusion Payments Are Not Needed to Settle Cases**

Pharmaceutical patent owners and generic firms can and do settle patent cases without exclusion payments. Several options are available to brand firms: (1) agree to let generics enter upon payment of a license fee; (2) agree with generics, based on the strength of the patent alone (not supplemented by exclusion payments) on a time of entry, or (3) take other actions that do not involve paying the generic to forego competition. *See* 1 Herbert Hovenkamp et al., *IP and Antitrust*, *supra* §15.2a1[C] (2d ed. & Supp. 2010) ("[T]he *ex ante* effect of a harsh rule will not necessarily impede settlement; it may simply make the settlement take on a different form."). The treatise authors endorse settlements of various forms that do not involve payment for delay.

The United States Supreme Court in *Actavis* likewise made clear that the risk of antitrust liability from an exclusion payment "does not prevent litigating parties from settling their lawsuit." *Actavis*, 570 U.S. at 158 ("[T]he fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit. They may, as in other industries, settle in other ways . . . ."). The Court pointed out that parties could pursue alternative forms of settlement, such as "allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Id*. These entry-date agreements, by which brands and generics divide the patent term by selecting a time for generic entry, tend to reflect the odds of success in patent litigation (and thus do not present similar antitrust concern).[8]

The Court went on to remark: "Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the [federal] antitrust laws are likely to forbid the arrangement." *Actavis*, 570 U.S. at 158. Economists have shown that an exclusion payment "that exceeds the patent holder's anticipated litigation costs is never necessary to secure a *desirable* settlement." Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 Tex. L. Rev. 283, 303, 328 (2012) (emphasis in original) (rebutting Robert D. Willig & John P.

[8] Hovenkamp et al., *IP and Antitrust*, *supra* § 15.3, at 15-45 (2d ed. & Supp. 2012).

Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 Antitrust Bull. 655 (2004)).

Indeed, empirical evidence makes it clear that abolishing exclusion payments does not prevent settlement. Since exclusion payments began receiving antitrust scrutiny, parties have continued settling their disputes, but in ways less restrictive of competition, such as through licenses allowing early generic entry. Such settlements have become typical; a recent FTC report showed that more than 85% of settlements do not involve payment or other compensation.[9]

Plaintiff's arguments that AB 824 will prevent settlement of patent disputes has been proven wrong. Generic pharmaceutical manufacturers argued to the *Actavis* Court that antitrust scrutiny of exclusion-payment settlements would make settlement impossible and force the parties to litigate patent disputes to verdict. *See, e.g.*, Br. for the Generic Pharm. Ass'n as *Amicus Curiae* Supporting Respondents 19, *FTC v. Actavis*, No. 12-416 (U.S. Feb. 28, 2013). Yet, after the *Actavis* Court rejected these arguments and held, for the first time, that such settlements are subject to antitrust liability, total settlements have *increased*, and, perhaps most telling, the number and percentage of settlements without exclusion payments have increased.[10] The fact that drug companies can and do settle litigation without exclusion payments, and that such settlements have increased with increased antitrust scrutiny of exclusion payments, belies any need to tolerate these anticompetitive payments.

### C. Not All Exchanges of Consideration to Settle Patent Lawsuits Are Illegal

Not every case in which an alleged infringer receives consideration in settlement of a patent lawsuit presents an exclusion payment that is anticompetitive or should be prohibited. After all, a generic company could receive *legitimate* consideration for settling in the form of a negotiated entry date allowing entry before the end of the patent term.

Entry-split agreements provide the generic with consideration that falls within the range of

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[9] FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2016* 1-2 (2019).

[10] *Id.*; *see* Dkt. 10-1(Mem. of Law in Support of Plaintiff's Motion for Preliminary Injunction) at 8 ("Since the Court decided *Actavis*, the total number of patent settlements has increased, but the number of anticompetitive settlements has decreased substantially.").

what could be expected in a patent lawsuit. If the brand wins the suit, it is able to exclude competition until the end of the patent term. If the generic wins, it is able to enter immediately. A compromise allowing the generic to enter before the end of the patent term, without a payment, thus falls within the range of expected outcomes in patent litigation and would not be subject to liability under AB 824.

## CONCLUSION

For all of the foregoing reasons, Plaintiff's Motion for Preliminary Injunction should be denied. Exclusion-payment settlements are unnecessary and are harmful to consumers and to competition. The *Actavis* Court set a floor, not a ceiling, on antitrust liability for these pernicious agreements.

Dated: December 10, 2019

Respectfully submitted,

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