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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Plaintiff,

v.

XAVIER BECERRA, in his official capacity as Attorney General of the State of California,

Defendant.

Case No. 2:20-cv-01708-TLN-DB

BRIEF *AMICI CURIAE* OF THE AMERICAN ANTITRUST INSTITUTE, CONSUMER REPORTS, INC., AND PUBLIC CITIZEN, INC. IN SUPPORT OF DEFENDANT

Judge: The Hon. Troy L. Nunley

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INTEREST OF *AMICI CURIAE*[1]

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.[2]

Consumer Reports, Inc. is an expert, independent, nonprofit organization, founded in 1936, that works side by side with consumers for a fair, transparent, truthful, and safe marketplace. It is the world's largest independent product-testing organization, using its dozens of labs, auto test center, and survey research department to rate thousands of products and services annually. It has been active for decades on a wide range of policy issues affecting consumers, including promoting competition in prescription drug and other markets, and supporting sound antitrust enforcement.

Public Citizen, Inc. is a nonprofit consumer advocacy organization that appears on behalf of its nationwide membership before Congress, administrative agencies, courts, and state governments on a wide range of issues. Among Public Citizen's longstanding concerns are promoting access to the affordable generic medications whose market entry the Hatch-Waxman Act was intended to promote, as well as maintaining the efficacy of the antitrust laws and other protections for consumers against collusive, manipulative, and anticompetitive commercial practices.

AAI, Consumer Reports, and Public Citizen submit this brief because the consumer harm caused by payments for delayed generic pharmaceutical entry supports AB 824's implementation and enforcement.

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[1] All parties consent to the filing of this *amicus* brief. No counsel for a party has authored this brief in whole or in part, and no party, party's counsel, or any other person—other than *amici* or their counsel—has contributed money that was intended to fund preparing or submitting this brief.

[2] Individual views of members of AAI's Board of Directors or Advisory Board may differ from AAI's positions.

INTRODUCTION AND SUMMARY OF ARGUMENT

This Court should reject the challenge to California's AB 824 brought by the generic pharmaceutical industry's trade association, the Association for Accessible Medicines (AAM), and deny AAM's request for a preliminary injunction.

Amici submit this brief to emphasize two issues. First, by helping to prevent anticompetitive reverse-payment settlements that subvert the Hatch-Waxman Act, AB 824 encourages earlier entry of generic drugs and lower drug prices for California patients, employers, union health plans, and taxpayers. Second, the statute is consistent with *Federal Trade Comm'n v. Actavis, Inc.*, 570 U.S. 136 (2013), *In re Cipro Cases I & II*, 348 P.3d 845 (Cal. 2015), and other cases following *Actavis* and *Cipro* that outlaw "pay for delay" deals. Consequently, AAM is not likely to succeed on the merits of its preemption and due-process arguments, and the balance of hardships favors the government. (*Amici* do not address the standing, ripeness, dormant Commerce Clause, and excessive fines issues.)

Both *Actavis*, under federal law, and *Cipro*, under California law, hold that it is anticompetitive for a brand-name drug manufacturer and its generic challenger to settle their patent litigation on terms pursuant to which the brand manufacturer makes a large, unjustified payment to the generic company (a reverse payment) and in exchange the generic company agrees to abandon its patent challenge and refrain for a period of time from competing by entering the market. *See Actavis*, 570 U.S. at 152, 158; *Cipro*, 348 P.3d at 867. Such a reverse-payment settlement is anticompetitive because it "likely seeks to prevent the risk of competition," which "constitutes the relevant anticompetitive harm." *Actavis*, 570 U.S. at 157.

A large, unjustified payment results in generic entry that is later than is warranted by the (expected) strength of the patent alone. *See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 404 (3d Cir. 2015) (payment delays entry "for longer than the patent's strength would otherwise allow"); *Cipro*, 348 P.3d at 865 (payment "eliminates competition beyond the point at which competition would have been expected"). Economics teaches that absent a reverse payment, the parties would agree to a settlement that provided earlier entry by the generic firm. *King Drug*, 791 F.3d at 405 & n.23; *Cipro*, 348 P.3d at 865. In the

unlikely event that settlement is not possible, continued litigation would be expected to result (on average) in earlier generic entry than a settlement that included a reverse payment. *King Drug*, 791 F.3d at 405; *Cipro*, 348 P.3d at 865. In any event, "[i]f the basic reason [for a reverse payment] is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement." *Actavis*, 570 U.S. at 158.

AAM seeks to wrap itself in the mantle of public interest, arguing that, contrary to the intent of the California legislature and the many consumer groups endorsing AB 824, the statute's restriction on reverse-payment settlements will actually lead to *less* generic entry and *higher* prescription drug prices. On the issue of reverse-payment settlements, AAM does not represent the interest of consumers. Indeed, as the Federal Trade Commission (FTC) explained, a fundamental problem with a reverse-payment settlement is that the "payment severs the alignment of interests that would otherwise exist between the generic manufacturer and consumers when the parties to paragraph IV litigation negotiate a settlement, and realigns the generic manufacturer's interests with the brand-name manufacturer's desire to preserve its monopoly." Reply Br. for the Petitioner at 21-22, *Actavis*, 570 U.S. 136 (No. 12-416), 2013 WL 1099171.

AAM's implausible argument that AB 824 reduces generic entry contradicts its claim that the statute is insufficiently protective of patent rights and brand-drug innovation. More significantly, it is based on the false premise that the statute has deterred procompetitive settlements. Consistent with *Actavis* and *Cipro*, AB 824 permits patent settlements that allow for entry before patent expiration (entry-only settlements) as long as they are not corrupted by a reverse payment. Moreover, AAM's argument that its members need the unfettered right to settle in order to make challenges profitable tends to confirm that the only settlements that may be deterred by the statute are anticompetitive ones. AAM made similar arguments in *Actavis*, but the evidence shows *Actavis*'s restrictions on reverse payments have reduced neither the overall number of settlements nor the number of patent challenges.

AAM's additional argument that AB 824 sharply conflicts with *Actavis* is wrong. AB 824

operates to ferret out anticompetitive reverse payments in a manner consistent with *Cipro*'s structured rule of reason analysis and with *Actavis*. Under *Cipro* and *Actavis*, a reverse payment is large and unjustified (and therefore anticompetitive) when it is greater than the brand firm's avoided litigation costs and the fair value of any goods or services provided by the generic to the brand firm. AB 824 follows this approach by defining a reverse payment as "anything of value" (excluding certain procompetitive forms of compensation), and then placing the burden on the defendant to show that the payment can be explained by avoided litigation costs (under defined conditions) or the other services. While *Actavis* held that the rule of reason applied, it contemplated a burden-shifting framework like that adopted by *Cipro* and lower federal courts which places the burden on the defendant to come forward with evidence of litigation costs or valuable collateral services that might explain the payment.

Like *Cipro* and *Actavis*, AB 824 limits the range of other potential procompetitive justifications, but allows defendants to show that the reverse-payment agreement has directly generated procompetitive benefits that outweigh the anticompetitive effects. AAM contends that the burden is impossible to satisfy but it does not identify procompetitive settlements that would be precluded. AAM argues that the statute does not recognize procompetitive benefits that may occur only in the future, but *Actavis* and *Cipro* also dictate an *ex ante* approach (based on forecasts and not actual results). AAM challenges the statute's presumption that the relevant market includes only the brand and its generic equivalents, but *Actavis* also presumed as much, and such relevant markets are common and proper in reverse-payment cases.

AAM's arguments that AB 824 conflicts with the Patent Act are also meritless. *Actavis* and *Cipro* make clear that patent law does not dictate whether or how a structured rule of reason or presumptions should apply to adjudicating claims that reverse-payment settlements violate antitrust law. Moreover, in providing that a reverse payment includes an exclusive license, AB 824 simply follows existing law whereby a promise by a brand firm not to compete by offering an "authorized generic" constitutes a reverse payment, whether the promise is part of an exclusive license or not. Likewise, AB 824's directive that a factfinder shall not presume patent validity in evaluating the competitive effects of the settlement is entirely consistent with *Actavis* and *Cipro*,

which are also agnostic as to the merits of patent validity.

ARGUMENT

I. BY RESTRICTING ANTICOMPETITIVE REVERSE-PAYMENT SETTLEMENTS, AB 824 IS LIKELY TO LOWER DRUG PRICES

Amici agree with AAM that the proliferation of generic drugs, facilitated by the Hatch-Waxman Act, has provided extraordinary savings to American patients and taxpayers.[3] But reverse-payment settlements, by delaying the entry of generic drugs, subvert the Hatch-Waxman Act and cost patients and taxpayers billions of dollars per year. *See* CA9.SER64[4] (FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010)). Indeed, a recent analysis estimates the cost of reverse-payment settlements before *Actavis* to be over $60 billion.[5]

A forgiving approach to reverse-payment settlements not only harms consumers by enabling brand-name drug manufacturers to thwart competition from cheaper drugs; it encourages brand manufacturers to invest less in developing new drug compounds or active ingredients protected by strong patents and more on making tweaks in formulations and changes in methods of use protected by weak secondary patents and reverse payments. *See* C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 Science 1386, 1387 (2013); *Cipro*, 348

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[3] *See In re Impax Labs., Inc.*, FTC No. 9373, 2019 WL 1552939, at *1 (Mar. 28, 2019) ("The Hatch-Waxman Act, together with other legislation at the federal and state levels, has facilitated a dramatic rise in sales of generic drugs, making them more widely available to Americans who would otherwise be forced to pay higher branded drug prices.") (internal quotation marks omitted), *appeal pending*, *Impax Labs., Inc. v. FTC*, No. 19-60394 (5th Cir.).

[4] Plaintiff's Memorandum of Law in Support of Plaintiff's Motion for Preliminary Injunction uses the designation "CA9.ER" to cite to the Excerpts of Record in *Ass'n for Accessible Medicines v. Becerra*, 822 F. App'x 532 (9th Cir. 2020), which was an appeal of a related case that has since been dismissed. *Amici* use the same designation to cite to the Excerpts of Record and also use the designation "CA9.SER" to cite to the Supplemental Excerpts of Record in that case.

[5] Michael Kades, *Competitive Edge: Underestimating the Cost of Underenforcing U.S. Antitrust Laws*, *Wash. Center for Equitable Growth* (Dec. 13, 2019), https://equitablegrowth.org/competitive-edge-underestimating-the-cost-of-underenforcing-u-s-antitrust-laws/. These estimates are based on the FTC's finding that settlements with payments delayed entry by 17 months on average as compared to settlements without payments. *See id.* Even a single anticompetitive settlement on a blockbuster drug can cost consumers billions of dollars. *See, e.g.*, FTC Mem. 5, *Fed. Trade Comm'n v. Cephalon, Inc.*, No. 2:08-civ-2141 (E.D. Pa. Feb. 17, 2015), 2015 WL 5583757 (calculating ill-gotten gain on the drug Provigil to be between $3.5 and $5.6 billion).

P.3d at 872 ("the broad availability of reverse-payment settlements favors weak patents and channels investment resources toward suboptimal innovation prospects"); *cf. New York v. Actavis* PLC, 787 F.3d 638, 659 (2d Cir. 2015) (noting that failing to condemn anticompetitive "product hopping" strategy "may deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations").

The Supreme Court's landmark *Actavis* ruling, which restricted reverse-payment settlements under federal antitrust law, has significantly reduced the number of *overt* pay-for-delay deals.[6] But *Actavis* has not eliminated reverse-payment settlements[7] nor prevented pharmaceutical companies from erecting roadblocks to its enforcement. *See* Assembly Committee on the Judiciary, Analysis of AB 824, at 13-14 (April 8, 2019) (quoting Consumer Reports's statement that "drug makers have continued to resist [*Actavis*], and to look for ways to evade it").

Although AB 824 was intended to shore up state antitrust restrictions on reverse-payment settlements so as to lower drug prices, and its passage was supported by dozens of consumer and other groups that advocate for lower prescription drug prices,[8] AAM contends that AB 824 will backfire and actually result in higher drug prices. AAM's Memorandum in Support of Motion for Preliminary Injunction (AAM Mem.) at 19. According to AAM, AB 824 will result in less generic entry because generic firms will be deterred from entering patent settlements and, as a result, will be deterred from bringing patent challenges in the first place. *Id*. at 13. AAM's argument that AB 824 insulates brand firms is hard to square with its claim that AB 824 "diminishes the value of a federally conferred patent" and "skews the delicate balance" between

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[6] *See* FTC Bureau of Competition, Agreements Filed with the Federal Trade Comm'n Under the Medicare Prescription Drug, Improvement and Modernization Act of 2003: Overview of Agreements Filed in FY 2016 (Nov. 2017) (FTC FY 2016 Agreements Report).

[7] The FTC's most recent analysis of settlements showed only one settlement with "explicit compensation" in excess of $7 million, but it also showed 14 settlements that contained one or more forms of "possible compensation." *Id*.

[8] *See* Senate Rules Committee, Office of Senate Floor Analysis, Analysis of AB 824, at 7-9 (Sep. 5, 2019) (noting that "bill is supported by a diverse coalition of health advocacy groups, labor and small business advocacy groups, and senior citizen advocacy groups, among others," and identifying 40 organizations in support); *see also* CA9.SER14–62 (numerous letters in support).

innovation and competition in favor of the latter. *Id.* at 11. In any event, AAM's argument that the California legislature, governor, attorney general and consumer groups have deluded themselves into mistakenly thinking that AB 824 benefits consumers is based on the false premise that AB 824 significantly deters procompetitive settlements.

By a procompetitive settlement, AAM appears to mean any settlement that enables a generic firm to enter the market before patent expiration. *See, e.g.*, *id.* at 1–2 (asserting that member "'would have received consideration and would have been allowed to bring its generic product onto the market' 'not immediately,' but 'prior to the expiration of the patent'" (quoting Ex. E ¶¶ 4-5)); *see also* CA9.ER166 (Decl. of Jack Silhavy ¶ 5). But AB 824 does not preclude such settlements, as this Court previously explained. *See* CA9.ER24 ("Surely, then, parties to pharmaceutical patent litigation *can* settle in the aftermath of AB 824."). Consistent with *Actavis*, AB 824 permits early-entry settlements as long as they are not corrupted by a reverse payment. *See* Cal. Health & Safety Code § 134002(a)(2)(A) (AB 824 codified as § 134002 (2019)); *cf. 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, for example, by 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."); *see also Cipro*, 348 P.3d at 868 (no-payment settlements are "ordinarily" available); *Impax*, 2019 WL 1552939, at *40 ("branded and generic pharmaceutical companies routinely—and far more often than not—settle patent litigation disputes without reverse payments").

To be sure, sometimes the generic and brand firms may not be able to reach an entry-date-only settlement because they have divergent views of the strength of the patent case. *See* CA9.ER142. However, such circumstances are uncommon.[9] And more significantly, a reverse payment designed to "bridge the gap" in the parties' positions is more likely to result in an

[9] *See* Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 Tex. L. Rev. 283, 291 (2012) (explaining that an entry-date-only settlement can always be reached if the generic firm is less sanguine about its chances of success than the brand firm).

anticompetitive entry date than continued litigation because a brand manufacturer will not pay for a result that is *worse* than it would expect to achieve in litigation. *See Cipro*, 348 P.3d at 869 n.17 ("Money may be needed to bridge the gap between the parties' expectations, but a rational brand asked to pay more than its litigation costs to persuade a generic with different perceptions [to agree to an entry date earlier than the brand firm's expected result in litigation] would, in the ordinary case, presumably just litigate.").[10]

Indeed, AAM's argument that the statute will bar settlements that generic manufacturers need in order to make challenges profitable *confirms* that any deterred settlements are likely to be anticompetitive ones. AAM maintains that because patent suits are expensive and "notoriously difficult for generic manufacturers to win," the "expected costs of litigating to judgment will thus often outweigh the expected value for the generic manufacturer." AAM Mem. at 4. As a result, it argues, "there is usually no viable alternative to settlement for lawfully bringing generic and biosimilar medicines onto the market in a timely manner." *Id.* at 18.

Put aside that AAM ignores the enormous incentive that the Hatch-Waxman Act provides a generic firm to be the first ANDA filer that enters the market[11] and that generics have a high likelihood of success in challenging the "follow on" patents that AAM rightly decries. (AAM Mem. at 4–5.)[12] AAM does not explain why a *brand* firm would settle a case that has a negative expected value for the generic manufacturer, let alone make a payment to settle such a case. And

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[10] Settlement, of course, is not an end in itself; settlement is desirable and procompetitive only if it can deliver to consumers their expected gains from litigation. *See Cipro*, 348 P.3d at 869 ("That some settlements might no longer be possible absent a [reverse payment] is of no concern if the ones now barred would simply have facilitated the sharing of monopoly profits.").

[11] *See Actavis*, 570 U.S at 143-44 (noting that first to file ANDA "will enjoy a period of 180 days of exclusivity (from the first commercial marketing of its drug)" that may be "worth several hundred million dollars," and account for the "vast majority of potential profits for a generic drug manufacturer") (internal quotation marks and citations omitted).

[12] *See* Hemphill & Sampat, *supra*, at 1387 (finding that reverse-payment settlements disproportionately focused on secondary patents and that generics win challenges to such patents more than two-thirds of the time); *see also* Henry Grabowksi et al., *Pharmaceutical Patent Challenges*, 3(1) Am. J. Health Econ. 33, 53 (2017) (finding generic win rate in cases that result in court decision of about 63% for method-of-use patents and 96% for formulation patents). AAM claims that generics "prevail far less than half the time" when cases are litigated to judgment. AAM Mem. at 4. However, even without distinguishing among the types of patent challenges, the data provided by AAM's prior declarations show about a 50% overall success rate. *See* CA9.ER 161–62, 171.

if generic firms are so economically vulnerable, then the reverse-payment settlements they reach are all the more likely to delay entry beyond what is warranted by the patent merits.[13]

The generics industry has cried wolf before, attempting this exact argument. In *Actavis*, the industry argued that "taking consideration off the table" would "make settlements more difficult and, in some cases, impossible to achieve." Br. for the Generic Pharm. Ass'n as *Amicus Curiae* at 19, *Actavis*, 570 U.S. 136 (No. 12-416), 2013 WL 769341. Moreover, the industry predicted that because patent challenges involve "significant litigation risk," restricting reverse-payment settlements "would decrease the number of challenges generic companies will be willing to make." *Id.* at 18, 19; *see also* Br. of Generic Mfgs. Upsher-Smith Labs, Inc., *et al*. as *Amicus Curiae* at 27, *Actavis*, 570 U.S. 136 (No. 12-416), 2013 WL 769339 ("reducing generic companies' ability to settle patent litigation . . . would cause generic companies to bring fewer patent challenges"). Yet while *Actavis*'s restriction on reverse payments significantly reduced the number of *problematic* patent settlements, *see supra* note 6, it did so without reducing the overall number of settlements or patent challenges. On the contrary, the overall number of settlements increased sharply in the three fiscal years following *Actavis*,[14] as did the number of patent-challenge cases.[15] Despite all the ink spilled on this issue over the years, AAM can point to no empirical evidence that restricting reverse payments deters procompetitive settlements or patent challenges.

In sum, AAM's argument that the statute will backfire and *increase* drug prices is as implausible as it sounds. AB 824 serves the purposes of the Hatch-Waxman Act, and the public interest strongly militates against a preliminary injunction.

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[13] *See* Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal*, 41 Rutgers L.J. 255, 306 (2009) (a generic firm's "economic vulnerability would place it in a poor bargaining position," giving brand manufacturer "little incentive to settle" and making generic firm more "likely to agree to date of entry well after the expected value date").

[14] *Actavis* was decided in June 2013. The average number of settlements reported to the FTC increased from 147 per year from FY 2011 to FY 2013 to 187 per year from FY 2014 to FY 2016. *See* FTC FY 2016 Agreements Report, *supra* note 6, Ex. 1.

[15] The average number of ANDA cases brought each year between 2014 and 2018 more than doubled from the period between 2009 and 2013. *See* Lex Machina Patent Litig. Report 5 (Feb. 2019); Kades, *supra*.

II. AB 824 IS CONSISTENT WITH *ACTAVIS* AND *CIPRO*

AAM's argument that AB 824 "impose[s] antitrust restrictions that go beyond the federal regulatory floor" and is inconsistent with patent law is wrong. AAM Mem. at 14–15. Rather, AB 824 was intended to be, and is, consistent with *Actavis* and with *Cipro*, which applied *Actavis*'s principles to California antitrust law. AAM's arguments to the contrary are based on a misreading of *Actavis* and AB 824.

A. AB 824's Presumption of Illegality Is Consistent with *Cipro*'s Structured Rule of Reason and *Actavis*

AAM contends that AB 824's presumption that reverse-payment agreements are anticompetitive is fundamentally at odds with *Actavis*'s adoption of the rule of reason for analyzing reverse payments. In denying AAM's first preliminary injunction motion, this Court properly rejected this argument, explaining that the presumption "is stronger, and the burden shift may be sharper, but both federal and state antitrust caselaw provides for a similar presumption and burden shift in the context of reverse payment settlement agreements." CA9.ER22.

To be sure, *Actavis* rejected the FTC's position that all reverse-payment settlements should be treated as presumptively unlawful. The Court concluded that a "quick look" analysis was not called for because, the Court said, "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." 570 U.S. at 159. But the Court also held that "a large, unjustified reverse payment risks antitrust liability," and it invited lower courts to "structur[e] the present rule-of-reason antitrust litigation" so as "to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on . . . the presence of significant unjustified anticompetitive consequences." *Id.* at 158, 159–60; *see also Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 898-99 (2007) ("[c]ourts can . . . devise rules over time for offering proof, or even presumptions where justified, to make the rule of reason a fair and efficient way to prohibit anticompetitive restraints"); Herbert Hovenkamp,

The Rule of Reason, 70 Fla. L. Rev. 81, 121 (2018) ("Antitrust cases are complex, and judges depend critically on presumptions and other evidentiary shortcuts.").

Consistent with the Supreme Court's invitation, *Cipro* adopted a structured rule of reason under the Cartwright Act, noting that its rule "is in harmony with *Actavis*, which offered only broad outlines and explicitly left to other courts the task of developing a framework for analyzing the anticompetitive effects of reverse payment patent settlements." *Cipro*, 348 P.3d at 871. *Cipro* provides:

> [1] To make out a prima facie case that a challenged agreement is an unlawful restraint of trade, a plaintiff must show the agreement contains both [a] a limit on the generic challenger's entry into the market and [b] compensation from the patentee to the challenger.
>
> [2] The defendants bear the burden of coming forward with evidence of litigation costs or valuable collateral products or services that might explain the compensation; if the defendants do so, the plaintiff has the burden of demonstrating the compensation exceeds the reasonable value of these.
>
> [3] If a prima facie case has been made out, the defendants may come forward with additional justifications to demonstrate the settlement agreement nevertheless is procompetitive.
>
> [4] A plaintiff who can dispel these justifications has carried the burden of demonstrating the settlement agreement is an unreasonable restraint of trade under the Cartwright Act.

Id.

AB 824 operates much like the burden-shifting framework adopted by *Cipro* and by lower federal courts under *Actavis*,[16] except that it provides more specificity. *See* Assembly Committee on Judiciary, *supra*, at 6, 11 (noting lack of "consistency and clarity" as to existing jurisprudence and that *Cipro* "test constitutes the basis for this bill"). As with *Cipro*, a plaintiff meets its initial burden under AB 824 by showing a reverse-payment agreement, namely a pharmaceutical patent

[16] *See, e.g., In re K-Dur Antitrust Litig.*, No. 01-cv-1652, 2016 WL 755623, at *13 (D.N.J. Feb. 25, 2016) (adopting *Cipro* framework for federal antitrust claim, finding its logic "compelling"); *In re: Androgel Antitrust Litig. (No. II)*, 1:09-MD-2084, 2018 WL 2984873, at *9 & n.74 (N.D. Ga. June 14, 2018) (holding that plaintiff satisfies its "burden in showing that the settlements violated the antitrust laws" by showing that settlement payment was "'large' relative to traditional settlement concerns," and rejecting argument that "this amounts to a 'quick look' test" rejected by *Actavis*); *see also Impax*, 2019 WL 1552939, at *18–19 (similar).

settlement involving: [a] a limit on the generic challenger's entry into the market, *see* § 134002(a)(1)(B) (the "nonreference drug filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the nonreference drug filer's product for any period of time"), and [b] compensation from the patentee to the challenger, *see* § 134002(a)(1)(A) ("anything of value"). And AB 824 clarifies that several forms of consideration do *not* constitute "anything of value."[17]

Cipro next places the burden of production on the defendants to show that avoided litigation costs or valuable collateral products and services may explain the reverse payment. *Cipro*, 348 P.3d at 866-67; *see Actavis*, 570 U.S. at 156 ("Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement."); *Impax*, 2019 WL 1552939, at *18 ("A 'large' payment is one that exceeds the value of the avoided litigation costs, plus any other services the generic drug manufacturer provides to the branded firm.").

AB 824 incorporates these potential justifications by defining "anything of value" to exclude compensation that is no more than the brand firm's avoided litigation expenses under specified conditions. § 134002(a)(2)(C).[18] And, it allows a defendant to avoid liability by showing that the reverse payment is "fair and reasonable compensation solely for other goods and

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[17] The statute exempts common procompetitive forms of consideration. For example, the statute makes clear that a brand manufacturer may grant the generic firm a license or covenant not to sue, not only on the patents at issue in the particular case, but also on other patents that could block the generic from entering the market. *See* §§ 134002(a)(2)(A), (B). *Cf. Impax*, 2019 WL 1552939, at *22 ("freedom to operate" license provided value to generic but was "inherently pro-competitive" and hence not part of "large and unjustified" payment). "Anything of value" also does not include: an acceleration clause that permits the generic firm to enter earlier than otherwise if the brand firm introduces a different form of the drug, § 134002(a)(2)(D); a clause providing that the brand firm will help, or not interfere with, the generic firm obtaining or maintaining regulatory approval, § 134002(a)(2)(E); or an agreement by which the brand firm forgives the potential damages accrued by the generic firm for an at-risk launch of the generic drug at issue, § 134002(a)(2)(F).

[18] To take advantage of this safe harbor the statute requires that avoided litigation costs be reflected in the brand manufacturer's budgets, and caps such costs at $7.5 million (or less where the generic firm's expected revenues are relatively small). § 134002(a)(2)(C). If the defendant cannot meet this test, it remains free to seek to rebut the presumption of illegality in other ways. *See* § 134002(a)(3).

services [the generic firm] has promised to provide." § 134002(a)(3)(A).[19] *Cf. Actavis*, 570 U.S. at 156 ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.").

Cipro recognized the "theoretical possibility that a settlement in excess of avoided litigation costs and collateral services could be procompetitive," and placed the burden on the defendants to come forward with any such justifications. 348 P.3d at 870.[20] Likewise, AB 824 allows a defendant to rebut the presumption of illegality by showing the settlement agreement "directly generated procompetitive benefits" and that the procompetitive benefits "outweigh the anticompetitive effects," even if the payment does not reflect avoided litigation costs or payment for other goods or services. § 134002(a)(3)(B). And, it clarifies that certain purported procompetitive benefits presumptively are not cognizable. *See* § 134002(b). Importantly, these non-cognizable "benefits" include those that *Actavis* and *Cipro* have rejected—such as the claim that a reverse-payment settlement is procompetitive if it allows generic entry before patent expiration[21]—but which the pharmaceutical industry continues to press here and elsewhere.[22] And *Actavis*, like *Cipro*, placed the burden on the defendants to establish the purported

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[19] Placing the burden of proof on the defendants on this issue is particularly appropriate given that "[c]onsiderable caution is in order in evaluating settlements that include side agreements for generic products or services," which may "be added to a patent settlement to provide cover for the purchase of additional freedom from competition." *Cipro*, 348 P.3d at 866; *see* Herbert Hovenkamp et al., *IP and Antitrust* § 16.01[D](III) (2018) (noting "increasing tendency of settling parties to complicate their settlements to dissuade antitrust scrutiny").

[20] The court declined to hold that reverse payments in excess of avoided litigation costs and collateral services are *per se* unlawful, noting, "Like the United States Supreme Court, we cannot say with reasonable certainty—yet—that we have posited every possible [other] justification that might render a particular reverse payment settlement procompetitive." *Cipro*, 348 P.3d at 870; *Actavis*, 570 U.S. at 156 ("There may be other justifications.").

[21] *See* § 134002(b)(1) ("the agreement's provision for entry of the [generic] before the expiration of any patent exclusivity" does not mean "that the agreement is pro-competitive"). Such a claim, if accepted, would resurrect the scope-of-the-patent test that *Actavis* rejected. *See Cipro*, 348 P.3d at 870 ("[a]n antitrust defendant cannot argue a settlement is procompetitive simply because it allows competition earlier than would have occurred if the brand had won the patent action"); *King Drug*, 791 F.3d at 406 (reverse-payment settlement is "not immunized, of course, simply because of . . . early-entry 'license'").

[22] *See, e.g.*, AAM Mem. at 3, 19; CA9.ER166 (Decl. of Jack Silhavy ¶ 5); *see also* Br. of AAM as *Amicus Curiae* at 26, *Impax*, No. 19-60396, 2019 WL 5296443.

procompetitive benefits. *See Actavis*, 570 U.S. at 158 ("one who makes such a payment" needs "to explain and to justify it"); *In re: Lipitor Antitrust Litig.*, 868 F.3d 231, 256–57 (3d Cir. 2017) ("The Supreme Court clearly placed the onus of explaining or justifying a large reverse payment on *antitrust defendants*.") (emphasis in original).

AAM argues that AB 824 makes it overly difficult for a defendant to rebut the presumption of illegality, citing among other things the requirement that a defendant show that the agreement "has directly generated procompetitive benefits." AAM Mem. at 6 (citing § 134002(a)(3)).[23] AAM has argued that this provision is problematic because "most patent settlements take years to be fully completed" and that "in many cases, a manufacturer will not be able to show that a settlement already has 'generated' benefits even though it undoubtedly will have procompetitive benefits over its lifetime." CA9.ER140 (emphasis omitted); *see* also AAM Mem. at 5 (objecting that statute "measures delay from the date a settlement is entered, not what would have happened if the parties had litigated the patent case to judgment"). But, this provision is consistent with the *ex ante* approach to analyzing reverse payments under *Actavis* and *Cipro* by which the anticompetitive effects and potential procompetitive benefits are assessed as of the time of the settlement.[24] And AAM has failed to identify any future *legitimate* procompetitive benefits recognized under *Actavis* and *Cipro* that the statute would foreclose.

AAM also points to AB 824's presumption that "the relevant product market" consists of the brand drug and its AB-rated generic equivalents, § 134002(c), contending that it "is a stark departure from long-settled law." AAM Mem. at 17. In fact, however, post-*Actavis* reverse-payment cases commonly have defined the relevant product market as limited to the brand drug

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[23] Notably, the statute sets a "preponderance of the evidence" standard for rebutting the presumption, § 134002(a)(3), rather than the "clear and convincing" standard that was originally proposed. *See* Assembly Committee on the Judiciary, *supra*, at 2 (summarizing original bill).

[24] *See also Apotex, Inc. v. Cephalon, Inc.*, 255 F. Supp. 3d 604, 611 (E.D. Pa. 2017) ("rule of reason analysis is conducted on an ex ante basis"); *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 337 (D. R.I. 2017) ("deal must be valued at the time the parties entered the deal"); *see generally* Herbert Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76 Ohio St. L.J. 467, 523 (2015) ("settlements as well as other licensing agreements must be analyzed ex ante, based on the parties' reasonable expectations, rather than ex post").

and its generic equivalents and/or found that the brand manufacturer had market power,[25] which is the issue at stake in market definition.[26] And such narrow product markets make sense precisely because only low-priced AB-rated generics—and not other therapeutic alternatives—drive down the price of the given drug. Indeed, both *Actavis* and *Cipro* recognize that a large, unjustified payment *itself* raises an inference of the brand manufacturer's market power. *See Actavis*, 570 U.S. at 157; *Cipro*, 348 P.3d at 869; *Impax*, 2019 WL 1552939, at *25 (*Actavis* "recognized that a branded drug and its generic equivalents could—and in the reverse payment context, often would—together constitute an antitrust-relevant market.").

B. AB 824 Does Not Conflict with the Patent Act

AAM also contends that AB 824 conflicts with the Patent Act because it "'upset[s] the federally struck balance'" between patent and antitrust policy. AAM Mem. at 12 (citation omitted). As demonstrated above, however, AB 824 is consistent with *Actavis*. Moreover, as this Court explained, the rule of reason adopted by *Actavis* "turns on questions of antitrust law, not patent law." CA9.ER15. The Court correctly followed *Cipro*, which rejected the argument that the test for analyzing reverse-payment settlements under state law must be no less "favorable to reverse payment patent settlement[s] . . . than would be the case under *Actavis*." 348 P.3d at 872. Rather, *Cipro* explained, "*Actavis* reverts solely to antitrust considerations" for "how such an examination is to be conducted," and "[w]here the choice of a test rests solely on economic considerations, no patent law preemption concerns arise." *Id.*; *see also Staley v. Gilead Sciences, Inc.*, No. 19-cv-02573-EMC, 2020 WL 1032320, at *24 (N.D. Cal. March 3, 2020) (holding that anticompetitive clause in patent settlement that provided significant benefit to the generic

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[25] *See, e.g., Impax*, 2019 WL 1552939, at *26; *United Food & Comm'l Workers Local 1776 v. Teikoku Pharma USA, Inc.*, 296 F. Supp. 3d 1142, 1176 (N.D. Cal. 2017); *In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 663 (D. Conn. 2016); *see also New York v. Actavis, PLC*, No. 14 Civ. 7473, 2014 WL 7015198, at *35 (S.D.N.Y. Dec. 11, 2014) ("As in this instance, courts have found a single brand-name drug and its generic equivalents to be a relevant product market in cases where the challenged conduct involves a branded drug manufacturer's effort to exclude generic competition.").

[26] "It must be remembered that articulating a relevant market definition is not an end in itself, but is in the service of answering the question of market power, which in turn 'is but a surrogate for detrimental effects." *Aggrenox*, 199 F. Supp. 3d at 668 (quoting *Fed. Trade Comm'n v. Indiana Fed. of Dentists*, 476 U.S. 447, 460–61 (1986)).

challenger could be unlawful even if it did not constitute a reverse payment under *Actavis*).

AAM's argument that AB 824 "conflicts directly" with provisions of the Patent Act that protect the rights of patent holders is also wrong. AAM Mem. at 10–11. AAM argues that § 134002(a)(1)(A), which clarifies that "anything of value" includes "an exclusive license or a promise that the brand company will not launch an authorized generic version of its brand drug," conflicts with the Patent Act's express allowance of exclusive licenses. *See id*. at 5, 10–11. It does not. "[E]ven exclusive licenses cannot avoid antitrust scrutiny when they are used in anticompetitive ways." *King Drug*, 791 F.3d at 407; *see Staley*, 2020 WL 1032320, at *16 ("[W]hat patent law permits (i.e., exclusive licenses) is not dispositive of legality for antitrust purposes."). Thus, courts uniformly hold that a brand company's promise not to compete by offering its own authorized generic drug is a reverse payment under *Actavis*,[27] whether the promise is explicit or implicit in an exclusive license.[28]

Finally, AAM contends that § 134002(b)(2), which provides that "the factfinder shall not presume" that "any patent is enforceable and infringed by the [generic] filer in the absence of a final adjudication binding on the filer on those issues," conflicts with the Patent Act's presumption that patents are valid. AAM Mem. at 6, 10–11. But this provision of AB 824—like others that limit justifications that go to the merits of the patent litigation, *see* §§ 134002(b)(1), (2), (4)—follows from *Actavis*'s recognition that the "relevant anticompetitive harm" from a reverse payment is "prevent[ing] the risk of competition." *Actavis*, 570 U.S. at 157. It is irrelevant to the antitrust analysis that a patent may be strong or is likely to be found valid and infringed under a presumption or otherwise. *See id.* (rejecting argument that avoiding "even a small risk of

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[27] *See King Drug*, 791 F.3d at 403; *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 550–552 (1st Cir. 2016); *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 717 (N.D. Ill. 2015); *United Food & Comm'l Workers Local 1776 v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1069–71 (N.D. Cal. 2014).

[28] AAM contends that the FTC has taken the position that "settlements with exclusive licenses and early-but-not-immediate entry tend to be procompetitive." AAM Mem. at 11. But the cited FTC brief takes the opposite position. *See* FTC *Amicus* Br. at 29–30, *Am. Sales Co. v. Warner-Chilcott Co., LLC*, 2015 WL 3957874 (1st Cir. June 16, 2015) (stating that "most exclusive licenses *in other contexts* raise no antitrust concerns," but that "any 'exclusive license' [that] would simply take the form of a No-AG commitment … does *not* promote competition and instead merely enlarges the pool of shared supracompetitive profits to the detriment of consumers.") (first emphasis added).

invalidity justifies a large payment"); *Cipro*, 348 P.3d at 863 (reverse-payment settlement may be anticompetitive "even when the patent is likely valid").

In *patent litigation*, the patent is presumed to be valid and not to be infringed.[29] In *antitrust reverse-payment litigation*, AB 824, like *Actavis* and *Cipro*, adopts an "agnostic stance toward" patent validity and infringement that is entirely consistent with the Patent Act. *Cipro*, 348 P.3d at 872. AB 824 does not assume (or presume) one way or another whether the brand manufacturer's patent is invalid or not infringed. Rather the statute appropriately presumes that a reverse payment is anticompetitive *regardless of the likely outcome of the patent litigation* because it delays entry beyond whatever the (expected) patent merits alone would dictate.

CONCLUSION

What *Actavis*, *Cipro*, and the cases following their leads—and empirical evidence—show is that reverse payments cause delay and higher prices. AB 824 is a valid legislative attempt to control anticompetitive behavior to benefit patients, employers, union health plans, and taxpayers. For the foregoing reasons, AAM's Motion for a Preliminary Injunction should be denied.

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Respectfully submitted,

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[29] *See Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91, 95 (2011) (infringement defendant must prove invalidity); *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 679 (Fed. Cir. 2008) (patentee bears ultimate burden of proving infringement).

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CERTIFICATE OF SERVICE

I, Eric B. Fastiff, hereby certify that on October 15, 2020, I electronically filed **BRIEF *AMICI CURIAE* OF THE AMERICAN ANTITRUST INSTITUTE, CONSUMER REPORTS, INC., AND PUBLIC CITIZEN, INC. IN SUPPORT OF DEFENDANT** attached to the accompanying Stutz Declaration with the Clerk of the United States District Court for the Eastern District of California using the CM/ECF system, which shall send electronic notification to all counsel of record.

/s/ Eric B. Fastiff
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