No. 20-15014

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

ASSOCIATION FOR ACCESSIBLE MEDICINES,
Plaintiff-Appellant,

v.

XAVIER BECERRA, in his official capacity as Attorney General of the State of California,
Defendant-Appellee.

On Appeal from the United States District Court for the Eastern District of California
(No. 2:19-cv-02281-TLN-DB)

BRIEF OF WASHINGTON LEGAL FOUNDATION, THE NATIONAL ASSOCIATION OF MANUFACTURERS, AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF-APPELLANT

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INTERESTS OF *AMICI CURIAE*[*]

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The National Association of Manufacturers (the NAM) is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 States. Manufacturing employs more than 12 million men and women, contributes annually $2.25 trillion to the U.S. economy, has the largest economic impact of any sector, and accounts for more than three-quarters of all private-sector research and development in the nation. The NAM is the voice of the manufacturing community and the leading

[*] No party's counsel authored any part of this brief. No one, apart from *amici* and their counsel, contributed money intended to fund the brief's preparation or submission. All parties have consented to the brief's being filed.

advocate for policies that help manufacturers compete in the global economy and create jobs across the United States.

The Chamber of Commerce of the United States of America (the Chamber) is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive branch, and the courts. To that end, the Chamber regularly files *amicus* briefs in cases that raise issues of concern to the nation's business community.

Amici agree that the American economy, individual freedom, and public health all suffer when state law, including state antitrust law, interferes with federal regulatory regimes, such as The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (Hatch-Waxman Act). Conflicting state and federal duties are not merely inefficient; they often make it impossible for

regulated parties to comply with both state and federal law without incurring massive liability.

The Supremacy Clause prevents the States from imposing liability for conduct that merely carries out federal policy. Yet under California Assembly Bill 824 (AB 824), drug innovators and generic manufacturers are no longer free in practice to do what federal law has long encouraged them to do: settle patent infringement suits to allow generic drugs to enter the market before the innovator's patent expires. By creating a presumption of unlawfulness when two companies negotiate a settlement that benefits both them and the public, AB 824 undermines federal law and stands as an obstacle to the explicit aims of Congress.

INTRODUCTION & SUMMARY OF ARGUMENT

Both innovator and generic drug manufacturers play a vital role in delivering life-saving drugs to the American public. If the quality of U.S. health care is to keep pace with scientific advances, innovator manufacturers that develop and bring to market new drugs must continue to enjoy predictable periods of patent protection during which potential competitors cannot market the same drug. At the same time,

once a branded drug's patent has expired, individual consumers and the greater public stand to benefit from the competition and lower price that a generic or biosimilar version brings. Federal policies facilitating generic and biosimilar market entry have made life-saving drugs more affordable for, and thus more accessible to, millions of Americans.

The success of the Hatch-Waxman Act, which governs generic entry, hinges on the availability of patent-infringement settlements between drug innovators and makers of generics. Under the Act, the FDA may approve a generic version of an already-approved brand-name drug based on a "showing that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Caraco Pharm Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). But the generic also "must assure the FDA that its proposed generic drug will not infringe the brand's patents." *Id.* at 406. One way to give that assurance is by filing "a so-called paragraph IV certification" that the innovator's patent "'is invalid or will not be infringed by the manufacture, use, or sale'" of the generic version. *Id.* at 407 (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012)). "Filing a

paragraph IV certification," however, "means provoking litigation," because the law "treats such a filing as itself an act of infringement." *Id.*

The process is much the same for biosimilars under the Biologics Price Competition and Innovation Act, Pub. L. No. 111-148, 124 Stat. 119, which likewise facilitates and encourages the early litigation (and settlement) of patent-infringement claims. 42 U.S.C. § 262(*l*). Because litigating infringement suits to judgment is costly, time-consuming, and risky, settling patent litigation, is the chief market-entry vehicle for low-cost generics and biosimilars.

The Supreme Court, in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), affirmed the vital role that pharmaceutical patent-litigation settlements play in delivering affordable drugs to Americans. Asked to adopt a presumption that such settlements are anticompetitive—the same presumption that AB 824 now enshrines into law—*Actavis* refused. 570 U.S. at 158-59. Instead, the Court instructed lower courts to analyze such settlements under a traditional "rule-of-reason" analysis. *Id.* In rejecting a per se rule of illegality and a "quick-look" approach that presumes anticompetitiveness, *Actavis* repeatedly emphasized the need to "balance" the competing interests of federal antitrust and patent law,

which are "both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent." *Id.* at 148.

Under *Actavis*'s rule-of-reason regime, the number of pharmaceutical patent settlements has increased. Press Release, FTC, *FTC Staff Issues FY 2016 Report on Branded Drug Firms' Patent Settlements with Generic Competitors* (May 23, 2019) <https://tinyurl.com/yyzola5q>. Even better, *Actavis*'s sensible approach to antitrust liability has "significantly reduced the kinds of reverse payment agreements that are most likely to impede generic entry and harm consumers." *Id.*

But the California State Assembly has other ideas. Contrary to *Actavis*, AB 824 presumes that every pharmaceutical patent settlement is anticompetitive and thus unlawful if it (1) gives a generic manufacturer "anything of value," including an "exclusive license," and (2) doesn't allow the generic to bring its product to market *immediately*. § 134002(a)(1) (ER 98). Every company that enters into a settlement on terms found to violate the law is liable for three times "California's share of the market for the brand drug at issue in the agreement."

§ 134002(e)(1)(A) (ER 100). Worse still, every "person" who merely "assists in" such a settlement must pay "a civil penalty" no less than $20 million, even if she never "received anything of value." *Id.* And unlike most state consumer-protection laws, AB 824 is not limited to California settlements; it purports to apply nationwide. *Id.*

Because the appellant is *more* than likely to prevail on the merits, the judgment below, denying an injunction, should be reversed. As the appellant has ably shown, by regulating the conduct of parties outside California, AB 824 flouts the Dormant Commerce Clause. What's more, the law's massive penalties, which target individuals as well as companies, likely violate the Eighth Amendment's Excessive Fines Clause. We write separately to emphasize that, by erecting major obstacles to the accomplishment of federal law, California's AB 824 frustrates the policy aims of Congress and is thus preempted.

First, AB 824 thwarts the Hatch-Waxman Act. In Hatch-Waxman, Congress confronted competing policy concerns—a desire to secure lower, more affordable drug prices for consumers, and a desire to provide enough financial incentives to spur research and development of new, life-saving drugs—and crafted a balanced solution. By

presuming the illegality of virtually every pharmaceutical patent settlement—Hatch-Waxman's primary market-entry vehicle for low-cost generics and biosimilars—AB 824, if left in place, will shrink the nation's supply of cheaper prescription drugs and "skew" Congress's "delicate balance of statutory objectives." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001).

Second, AB 824 severely undercuts federal patent law. As with all forms of private property, the right to one's own inventions is only as strong as one's ability to enforce that right against the world. Under federal law, therefore, "[a] patent shall be presumed valid." 35 U.S.C. § 282(a). Yet under California law, a factfinder may *never* presume "[t]hat any patent is enforceable." AB 824, § 134002(b)(2) (ER 99). AB 824 thus ignores federal patent rights, erecting an untenable presumption of illegality, and imposing harsh penalties, on routine pharmaceutical patent settlements that grant a lawful patent license even one day in the future.

Third, by eroding the incentives that allow low-cost generics and biosimilars to enter the market, AB 824 undermines the central goal of antitrust law—to promote consumer welfare. Beyond that, the law

ignores the reality that the value of protecting valid patents is not just pro-patent, but *pro-competitive*. Settling infringement claims fosters competition by innovators in part by allowing them to avoid the risk of erroneous patent invalidation. By ignoring the procompetitive aspects of patent protection, and by forcing generic manufacturers to assume extraordinarily high litigation risks and costs when challenging a patent, AB 824 contravenes the fundamental purpose of antitrust law—to promote competition. The resulting overdeterrence will not only upend federal drug policy and federal patent rights, it will harm competition itself.

Fourth, AB 824 is a recipe for protracted and costly patent litigation. *Actavis* emphasized that the antitrust scrutiny applied to so-called reverse payments "does not prevent litigating parties from settling their lawsuit" in part because settlement might enable "the generic manufacturer to enter the patentee's market prior to the patent's expiration." *Actavis*, 570 U.S. at 158. AB 824 contravenes this broader federal policy "favoring the settlement of disputes" and diminishes "the value of settlements" in curbing the "patent litigation problem." *Id.* at 153.

ARGUMENT

AB 824 Undermines Federal Law And Interferes With Congress's Explicit Policy Aims In Several Discrete Ways.

Under the Supremacy Clause, a state law that "upset[s] [a] careful balance struck by Congress" is preempted. *Edgar v. MITE Corp.*, 457 U.S. 624, 634 (1982). California law must give way to federal law when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. 387, 399 (2012). AB 824 poses discrete obstacles to Congress's aims under federal food-and-drug law, federal patent law, and federal antitrust law. It cannot stand.

A. AB 824 Disrupts The Hatch-Waxman Act.

The Hatch-Waxman Act amended both the Federal Food, Drug, and Cosmetic Act and the federal patent laws. It embodies Congress's deliberate attempt to "benefit makers of generic drugs, research-based pharmaceutical companies, and not incidentally the public." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997). The Act strikes "a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market."

Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed Cir. 2002). California's AB 824 upsets that delicate balance.

The FDA's lengthy drug-approval process typically prevents the marketing of a new drug—and the earning of a profit—for many years after a patent issues. To compensate for that regulatory lag time and encourage drug innovation, the Act in some cases grants patent-term extensions to brand-name drug makers. *See* 35 U.S.C. § 156. In extending the patent term for innovator drugs, Congress sought to "create a new incentive for increased expenditures for research and development" of new, life-saving therapies. H.R. Rep. No. 98-857, pt. 1 at 15 (1984), *reprinted in* 1984 USCCAN 2647, 2670.

The Act also spurs generic entry by creating the Abbreviated New Drug Application (ANDA) process, which greatly streamlines FDA approval of a generic manufacturer's application to market a generic copy of a branded drug upon the patent's expiration. 21 U.S.C. § 355(j). The ANDA process also allows generic manufacturers to save vast amounts of time and money by relying on the branded manufacturer's safety and efficacy studies, so long as the generic maker can show that its drug is bioequivalent to the approved, branded drug. This

supersedes any requirement that the generic manufacturer independently show, through multiple clinical studies, that its drug is safe and effective.

Under paragraph IV of the Act, generic applicants must certify that the innovator's patent "is invalid or will not be infringed" by the "manufacture, use, or sale" of the generic version. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012). Because filing a paragraph IV certification is an act of infringement against a validly patented drug, the Act enables generic manufacturers to force the innovator company into immediately filing an infringement suit. In other words, the Act allows makers of generics to place a patent's validity in doubt without being exposed to the potentially bankrupting damages normally at stake in patent litigation. In short, Congress intended the ANDA process to "make available more low-cost generic drugs by establishing a generic drug approval procedure for pioneer drugs." H.R. Rep. No. 98-857, pt. 1 at 14, 1984 USCCAN at 2647.

"Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming." *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976). The alleged

infringer faces the potential for an enormous damages award, while a patent holder faces the possibility that its patent will be found invalid or unenforceable. Under Hatch-Waxman, "[v]irtually every patent license can be viewed as a settlement of a patent dispute." Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391, 392 (2003).

Because the generic entrant will charge a lower price than the innovator charges, the parties to these settlements place markedly different values on the duration of any license. There often is no specific entry date that both can readily accept. *See* Mark G. Schildkraut, *Patent Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1067 (2004). What's more, differing assessments of the strength of the patent and differing attitudes toward risk widen the settlement gap—thus requiring something "of value" to close it.

The availability of Hatch-Waxman settlements thus fosters more patent challenges and more competition in the long run, by reducing the generic manufacturer's costs as well as risks. The more Paragraph IV challenges, the more settlements. The more settlements, the more generic drugs will be able to enter the market. But a generic

manufacturer's incentives to file a Paragraph IV challenge depend on its having the flexibility to decide when, and on what terms, to resolve the litigation rather than engage in a multi-million dollar fight to the death in every case. AB 824 upends those incentives.

Again, so long as patent litigation is still pending, generic manufacturers are reluctant to market their drugs, even after obtaining FDA approval of their ANDAs, given the risk of exposure to massive infringement damages. If the generic competitor is found to have infringed an unexpired patent, its liability for repayment of the innovator's lost profits would dwarf any profits it would have derived at selling the drug at a reduced price. Given those stakes, the ability to settle patent-infringement suits is vital for generics to enter the market *before* patent expiration.

Yet under AB 824, each party to a Hatch-Waxman settlement faces an astronomical penalty if the agreement includes any licensing term that arguably delays the generic challenger's entry date. To comply with California law, a patent settlement not only must include a license that begins *immediately*, but a license that includes nothing else "of value"—which the statute says includes an "exclusive license." By

presuming that any other kind of settlement is illegal, AB 824 erodes any incentive to challenge patents by eroding the generic company's settlement options when the patentee sues for infringement. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 256 (E.D.N.Y. 2003) ("[A] generic company should be permitted to choose not only when to commence patent litigation, but also when to terminate it. Otherwise, the incentives to mount an ANDA IV challenge could be reduced.").

If an innovator cannot give "anything of value" to a generic—including, for example, a contractual promise to forgo potential infringement damages vis-à-vis a patent other than the one in dispute—without facing legal jeopardy and massive penalties, there may never be another settlement of Hatch-Waxman litigation. Under AB 824, virtually no lawful settlement term exists that a generic would find acceptable. "If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation).

AB 824's ultimate effect on the pharmaceutical market is unmistakable: fewer generics and higher drug prices. Under AB 824, the Hatch-Waxman Act's incentive structure can no longer overcome the enormous cost, time, and risk required to successfully prosecute *or* defend a patent-infringement suit to judgment. Because generic companies cannot reliably settle costly and time-consuming patent litigation without fear of being sued in state court and incurring astronomical penalties, they will file fewer ANDAs for FDA-approved drugs whose patents have not yet expired. And even for those ANDAs already in the litigation pipeline, innovator companies will be less likely to commit many billions of dollars to funding the research and development of new, life-saving drugs if they can no longer leverage their federal patent rights to safeguard their investment. Consumers and innovation will both suffer.

In sum, by effectively outlawing most pharmaceutical patent settlements, AB 824 undermines Congress's entire goal in the Hatch-Waxman Act. If California deliberately set out to stifle drug innovation and constrict America's supply of generic, low-cost drugs, AB 824 would fit the bill.

B. AB 824 Drastically Undercuts Federal Patent Law.

Federal patent law is "the supreme law of the land." *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964). "Just as a State cannot encroach upon the federal patent laws directly, it cannot, under some other law, such as that forbidding unfair competition, give protection of a kind that clashes with the objectives of the federal patent laws." *Id.*, at 231. Yet AB 824 "work[s] a revolution in patent law." *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005). The Supremacy Clause won't abide that.

"The grant of a patent is the grant of a statutory monopoly." *Sears, Roebuck & Co.*, 376 U.S. at 229. Indeed, the "essence of a patent grant" is "the right to exclude others from profiting by the patented invention." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). Patents are "more important to foster innovation in the pharmaceutical industry than in most other industries." W. Kip Viscusi, *et al.*, The Economics of Regulation & Antitrust 886 (4th ed. 2005). Under the Patent Act, a drug patentee has the exclusive right to manufacture, use, and sell his invention for up to 20 years. *See* 35

U.S.C. § 154(a)(1) ("grant[ing] to the patentee" the "right to exclude others from making, using, offering for sale, or selling the invention").

A patentee's right to license its patented invention is one of the oldest and most secure of all patent rights. A patentee may grant one exclusive license, many licenses, or none at all. It may restrict any license term that does not extend the patent. It may tell the licensee when it may sell, where it may sell, to whom it may sell, and how much it may sell. *See, e.g.*, *Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964) ("A patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly."); *United States v. Gen. Elec. Co.*, 272 U.S. 476, 489 (1926) ("[T]he patentee may grant a license * * * for any royalty or upon any condition the performance of which is reasonably within * * * the patent.").

In maintaining a uniform patent system, Congress recognizes the value of temporary restraints on trade to spur innovation. "The patent laws—unlike the Sherman Act—do not aim to maximize competition (to a large extent, the opposite)." *Kimble v. Marvel Entm't*, 135 S. Ct. 2401, 2413 (2015). While such restraints cut against the normal goals of antitrust law, Congress has insisted that courts not apply antitrust law

in a way that shortchanges the rights of patent holders. *See, e.g.*, *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964) (explaining that federal patent laws "are *in pari materia* with the antitrust laws and modify them *pro tanto*").

The federal patent laws thus embody Congress's "careful balance between the need to promote innovation and the recognition that imitation and refinement are both necessary to invention itself and the very lifeblood of a competitive economy." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). The State of California cannot alter that balance.

Nor does anything in the Hatch-Waxman Act, or its enactment history, abridge traditional patent protections. The law's legislative history confirms as much. As Congressman Waxman explained, "as a matter of public policy we, under the patent law, give that protection to the person who has put money into research and development for an innovative and new product." 130 Cong. Rec. 24,427 (Sept. 6, 1984); *see also* H.R. Rep. No. 98-857, pt. 1, at 28 (1984) ("The provisions of this bill * * * are not intended to modify existing patent law with respect to the

burden of proof and the nature of proof to be considered by the courts in determining whether a patent is valid or infringed.").

AB 824 makes a hash of federal patent rights. It condemns run-of-the-mill patent-litigation settlements as presumptively illegal. And it condemns "an exclusive license" as presumptively anticompetitive. Yet any law that eliminates—or even frustrates—a patent holder's ability to negotiate with potential infringers renders the patent less valuable. The result is that innovator drug companies may be less willing to commit many billions of dollars to funding the research and development of new, life-saving drugs if they cannot leverage their federal patent rights to recoup their investment.

"The United States Supreme Court is the final arbiter" of "the extent to which interpretations of antitrust law—*whether state or federal*—must accommodate patent law's requirements." *In re Cipro Cases I & II*, 348 P.3d 845, 859 (Cal. 2015) (emphasis added). If the Supreme Court, applying federal patent law, requires "deference to patents' presumed validity and the consecration of a broad range of agreements otherwise facially illegal under state law," then California

"must abide by that judgment." *Id.* Of course, such "deference" is precisely what *Actavis* requires.

Actavis drew a clear line between settlements involving those "traditional," "familiar," and "commonplace" "settlement considerations" explicitly authorized by the patent laws (and *not* subject to antitrust scrutiny), and those involving "large and unjustified reverse payment[s]" (which *may* be subject to antitrust scrutiny). 570 U.S. at 154-58. If the settlement "reflects traditional settlement considerations, such as avoided litigation costs or fair value for services," there is little "concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." *Id.*

A unanimous Supreme Court has also rejected bright-line rules that, like AB 824's presumption of invalidity, would undermine the settled expectations of inventors and patentees. *See, e.g.*, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002) ("Fundamental alterations in these rules risk destroying the legitimate expectations of inventors in their property."). Yet under AB 824, even a settlement explicitly blessed by the Supreme Court—*i.e.*, one "allowing the generic manufacturer to enter the patentee's market" at a future

date "prior to the patent's expiration, without the patentee paying the challenger," *Actavis*, 570 U.S. at 158—is presumed unlawful if the entry comes with "an exclusive license." AB 824, § 134002(a)(1) (ER 98).

Both the Constitution and Congress authorize the granting of exclusive patents to encourage innovation and to secure financial rewards for inventors of new prescription drugs. AB 824 undercuts that purpose by penalizing patentees for merely exercising the very property rights Congress bestows on them.

C. AB 824 Upends Federal Antitrust Law.

As shown above, the ultimate effect of AB 824 will be to reduce the availability of low-cost generics and biosimilars, raising drug prices on consumers in the long run. But lowering prices "is the very essence of competition." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986). Beyond the salutary effect of lowering prices for goods and services, price competition increases outputs, decreases deadweight losses, and benefits consumers. *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 340 (1990) ("Low prices benefit consumers regardless of how those prices are set, and so long as they are above predatory levels, they do not threaten competition."). By reducing the

availability of low-cost generics on the market, AB 824 will undermine the central goal of antitrust law—to promote consumer welfare.

Nor is that all. Antitrust law directs itself "not against conduct which is competitive," but "against conduct which unfairly tends to destroy competition itself." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993). Again, by presuming harm to competition even in a mine-run patent infringement settlement, AB 824 erodes federal patent rights. Yet the benefits of protecting valid patents are not simply pro-patent, but *pro-competitive*. AB 824 thus upends federal antitrust policy as well as federal patent policy.

Under federal antitrust law, the existence of the patent, and the right it grants the patentee to exclude infringers, controls the antitrust analysis for a simple reason: "We do not want an efficient market in stolen goods." Richard A. Posner, *Economic Analysis of Law* 91 (5th ed. 1998). Just as the antitrust laws do not protect unlawful competition, the public is "not entitled to profit by competition among infringers." *Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.*, 154 F. 358, 364 (7th Cir. 1907).

Settling infringement claims thus fosters competition in part by avoiding the risk of *erroneous* patent invalidation. When a brand-name manufacturer holds a strong patent, it is likely to procure a favorable settlement, *as it should*, to preserve the incentives to innovate that benefit consumers in the long run. Erroneous patent invalidation harms consumers. "[I]f the settlement prevents infringing entry, such prevention in itself is a *pro-competitive* effect." Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir. B.J. 617, 622 (2006) (emphasis added).

Rather than heed patent rights, however, AB 824 simply assumes the answer to the question being litigated and settled: whether the innovator's patent is valid. True, if we knew in advance that the patentee would lose its infringement suit, the State of California's presumption of unlawfulness might hold. But it is equally true that, if we knew the patentee would win, yet the generic was entitled to immediate market entry, the long-term competitive interest of consumers would be precisely the opposite. That is, if the generic

product would infringe a valid patent, consumers would suffer by early, but anticompetitive, generic entry. *Actavis*, 570 U.S. at 147-48.

Put differently, an antitrust policy that slashes prices today at the expense of even a slight annual reduction in the rate of innovation "would be a calamity." Frank H. Easterbrook, *Ignorance and Antitrust*, in *Antitrust, Innovation, and Competitiveness* 119, 123 (Thomas M. Jorde & David J. Teece eds., 1992). Federal antitrust law cannot abide "an analytical model in which the benefits of price competition on one side of the equation are taken into account, but the benefits of innovation on the other side of the equation are not." Bernard & Tom, *supra*, 15 Fed. Cir. B.J. at 621. Only by embracing that mistaken assumption is it "easy to get to a conclusion of presumptive illegality." *Id*. at 622.

California's logic—that consumer welfare requires pharmaceutical patent holders in patent disputes to litigate to verdict rather than settle—conjures a competitive interest unknown to antitrust. Under federal antitrust law, if a patent is valid, "the pioneer manufacturer is entitled to its monopoly profit, and a settlement that merely transfers a portion of that profit to a potential generic manufacturer *causes no*

harm." Thomas B. Leary, Antitrust Issues in Settlement of Pharmaceutical Patent Disputes, 14 ABA Antitrust Healthcare Chron. 1, 6 (Winter 2000/2001) (emphasis added).

True enough, a patentee is not entitled to "protection from competition which the patent law, unaided by restrictive agreements, does not afford." *United States v. Masonite Corp.*, 316 U.S. 265, 279 (1942). But the mere fact that California prefers a settlement that it finds "more competitive" is not enough to show that the parties' settlement is unreasonable, much less unlawful. *See Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16 (2004) ("The Sherman Act * * * does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition." (internal quotation and citation omitted)). Patent litigants "who wish only to settle the present litigation" are not required "to act as unwilling private attorneys general." *Nestle Co. v. Chester's Market, Inc.*, 756 F.2d 280, 284 (2d Cir. 1985).

California is free, of course, to adopt a more *relaxed* standard of antitrust review. It may, for example, adopt the "scope of the patent

test" that the *Actavis* dissent found more appropriate. 570 U.S. at 160-77. But by imposing a standard of review that is *more exacting* than the rule of reason, California upends a deliberate balance Congress has carefully maintained between federal antitrust and federal patent law. This it cannot do.

While "Congress intended the federal antitrust laws to supplement, not displace, state antitrust remedies," *California v. ARC Am. Corp.*, 490 U.S. 93, 102 (1989), even state antitrust laws are preempted when they "upset [a] federally struck balance" of competing policies. *Morseburg v. Balyon*, 621 F.2d 972, 977 (9th Cir. 1980). As here, "state antitrust law" is preempted if "it creates a substantial risk of conflict with policies central to" federal law. *Connell Constr. Co. v. Plumbers & Steamfitters Local Union No. 100*, 421 U.S. 616, 635-36 (1975).

If anything, *Actavis*'s repeated use of the word "balance," 570 U.S. at 148, and its emphasis on "accommodat[ing] patent and antitrust policies," *id.* at 148, 151, makes clear that any state law that upends that balance thwarts the will of Congress. *See City of Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624, 638-39 (1973) (finding state

antitrust law preempted when federal law "requires a delicate balance [and] a uniform and exclusive system of federal regulation if the congressional objectives * * * are to be fulfilled"); *cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501 (1996) (refusing to find preemption where the federal scheme at issue was not one "in which the Federal Government has weighed the competing interests relevant to the particular requirement in question" and "reached an unambiguous conclusion about how those competing considerations should be resolved").

At bottom, AB 824 contravenes the overriding aim of all federal antitrust law—to promote competition. "[S]alutary and procompetitive conduct * * * might be shunned by businessmen who chose to be excessively cautious in the face of uncertainty." *United States v. U.S. Gypsum Co.*, 438 U.S. 422, 441 (1978). If allowed to stand, AB 824 would subject lawful ventures to the formidable threat of antitrust liability, thereby "chill[ing] the very conduct the antitrust laws are designed to protect," *Matsushita Elec. Indus.*, 475 U.S. at 594, and creating "irrational dislocations in the market." *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 764 (1984).

The "resulting danger is that courts will prohibit, or the antitrust authorities will prosecute, acts that *appear* to be anticompetitive but really are the opposite." William J. Baumol & Alan S. Blinder, *Economics: Principles and Policy* 241 (12th ed. 2012) (emphasis in original). This overdeterrrence is not only corrosive to the workings of our economy; it is out of step with federal policy.

D. AB 824 Discourages The Efficient Settlement Of Patent Disputes.

Federal law "favors and encourages compromise settlements." *United States v. McInnes*, 556 F.2d 436, 441 (9th Cir. 1977); *see also id.* ("[T]here is an overriding public interest in settling and quieting litigation."); Fed. R. Civ. P. 68 (reflecting a federal policy "to encourage settlements and avoid protracted litigation"). Yet AB 824 condemns and penalizes the efficient settlement of many patent disputes. That's an invitation for more, not less, litigation.

In 2019, a company's median litigation cost in a patent-infringement suit was between $1.86 million and $5.2 million, depending on the value of the patent. *See* Am. Intell. Prop. L. Ass'n, 2019 Rep. of the Econ. Survey ("AIPLA Report"), at 56 (2019). For highly valuable patents, infringement litigation can create massive

exposure. "In bet-the-company cases, the average exposure for large companies is over $1 billion, with the high-end at $2 billion." Morrison & Foerster LLP, *Benchmarking IP Litigation 2019*, at 3 (2019) <https://tinyurl.com/uhwafoe>. It is no surprise, therefore, that "patent cases have produced some of the largest damages awards in history." Steven C. Carlson, *Patent Pools and the Antitrust Dilemma*, 16 Yale L.J. on Reg. 359, 380 (1999).

Settling patent disputes furthers the venerable goal of minimizing litigation. Settlements save litigants (and the judiciary) the time and expense of trial, even if the verdict properly would have upheld *or* invalidated the patent. *Bradley v. Chiron Corp.*, 136 F.3d 1317, 1322 (Fed. Cir. 1998) ("[S]ettlement reduces costs for all parties, conserves judicial and private resources, and promotes good will."); *see Marek v. Chesny*, 473 U.S. 1, 10 (1985) ("And, even for those who would prevail at trial, settlement will provide them with compensation at an earlier date without the burdens, stress, and time of litigation.").

Actavis affirmed "a general legal policy favoring the settlement of disputes" and "the value of settlements" in curbing the "patent litigation problem." 570 U.S. at 153. In contrast, AB 824 casts a cloud of

crushing liability over such settlements, making a trial on the merits much more likely. Such protracted patent litigation is extraordinarily inefficient and expensive, posing significant risks for patent holders and alleged infringers alike. Beyond the violence it does to federal law, then, AB 824 invites endless litigation and threatens to deplete precious judicial resources.

CONCLUSION

The district court's judgment should be reversed.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify:

(i) That this brief complies with the page limit set forth in Circuit Rule 29-2(c)(2). The brief contains 5,792 words.

(ii) That this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6), because it has been prepared using Microsoft Office Word 2010 and is set in 14-point Century Schoolbook font.

February 6, 2020

/s/ Cory L. Andrews

CERTIFICATE OF SERVICE

I certify that on February 6, 2020, I filed the foregoing *amicus curiae* brief via the CM/ECF system and served the foregoing via the CM/ECF system on all counsel who are registered CM/ECF users.

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