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

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TABLE OF CONTENTS

TABLE OF AUTHORITIES ii

INTRODUCTION 1

ARGUMENT 2

I. AAM Is Likely To Succeed On The Merits 2

A. AAM's "Pre-Enforcement" Commerce Clause Claim Is Ripe 2

B. AB 824 Violates the Commerce Clause As Applied To Settlements Completed Wholly Out of State 9

C. AB 824 Is Preempted 18

D. AB 824 Violates the Excessive Fines Clause 23

E. AB 824 Violates Due Process 26

II. AAM Satisfied The Remaining Preliminary-Injunction Factors 28

CONCLUSION 30

CERTIFICATE OF COMPLIANCE

CERTIFICATE OF SERVICE

TABLE OF AUTHORITIES

Cases

Amgen Inc. v. Sandoz Inc.,
877 F.3d 1315 (Fed. Cir. 2017) 24, 29

Ass'n for Accessible Meds. v. Frosh,
887 F.3d 664 (4th Cir. 2018) 17, 22

Babbitt v. United Farm Workers Nat'l Union,
442 U.S. 289 (1979) 3

Baldwin v. G.A.F. Seelig, Inc.,
294 U.S. 511 (1935) 18

Bonito Boats, Inc. v. Thunder Craft Boats, Inc.,
489 U.S. 141 (1989) 24

Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.,
476 U.S. 573 (1986) 15, 22

Buckman Co. v. Pls.' Legal Comm.,
531 U.S. 341 (2001) 24, 27, 29

Craig v. Boren,
429 U.S. 190 (1976) 3

Daniels Sharpsmart, Inc. v. Smith,
889 F.3d 608 (9th Cir. 2018) 15, 17

Edgar v. MITE Corp.,
457 U.S. 624 (1982) 11, 22

FTC v. Actavis, Inc.,
570 U.S. 136 (2013) 25

Healy v. Beer Inst.,
491 U.S. 324 (1989) .... passim

Holder v. Humanitarian Law Project,
561 U.S. 1 (2010) 8, 10

In re Brand Name Prescription Drugs,
123 F.3d 599 (7th Cir. 1997)....................20

In re Cipro Cases I & II,
348 P.3d 845 (Cal. 2015) 25, 34

In re Lipitor Antitrust Litig.,
868 F.3d 231 (3d Cir. 2017)....................24

In re Loestrin 24 Fe Antitrust Litig.,
814 F.3d 538 (1st Cir. 2016) 24

In re Lorazepam & Clorazepate Antitrust Litig.,
295 F. Supp. 2d 30 (D.D.C. 2003) 19

Knevelbaard Dairies v. Kraft Foods, Inc.,
232 F.3d 979 (9th Cir. 2000)....................19

Legend Night Club v. Miller,
637 F.3d 291 (4th Cir. 2011)....................36

Maryland v. King,
567 U.S. 1301 (2012)....................35

Melendres v. Arpaio,
695 F.3d 990 (9th Cir. 2012)....................36

Milavetz, Gallop & Milavetz, P.A. v. United States,
559 U.S. 229 (2010)....................8

Morseburg v. Balyon,
621 F.2d 972 (9th Cir. 1980)....................23

Nat'l Audubon Soc'y, Inc. v. Davis,
307 F.3d 835 (9th Cir. 2002)....................5, 6

Nat'l Fed'n of Indep. Bus. v. Sebelius,
567 U.S. 519 (2012)....................3

NIFLA v. Harris,
839 F.3d 823 (9th Cir. 2016), *adopted in relevant part and rev'd on other grounds*,
138 S. Ct. 2361 (2018)....................4

Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.,
719 F.3d 1346 (Fed. Cir. 2013)....................27

People v. Steward,
228 Cal. Rptr. 3d 877 (Cal. Ct. App. 2018)....................13

Pharm. Research & Mfrs. of Am. v. Concannon,
249 F.3d 66 (1st Cir. 2001)....................17

Pharm. Research & Mfrs. of Am. v. D.C.,
406 F. Supp. 2d 56 (D.D.C. 2005)....................17

Pharm. Research & Mfrs. of Am. v. Walsh,
538 U.S. 644 (2003)....................16

Rocky Mountain Farmers Union v. Corey,
730 F.3d 1070 (9th Cir. 2013).................... 20, 21

Rosenblatt v. City of Santa Monica,
940 F.3d 439 (9th Cir. 2019)....................13

Sam Francis Found. v. Christies, Inc.,
784 F.3d 1320 (9th Cir. 2015)....................15

Speiser v. Randall,
357 U.S. 513 (1958)....................34

Susan B. Anthony List v. Driehaus,
573 U.S. 149 (2014).................... 3, 7, 9

Tenn. Wine & Spirits Retailers Ass'n v. Thomas,
139 S. Ct. 2449 (2019)....................22

Thomas v. Anchorage Equal Rights Comm'n,
220 F.3d 1134 (9th Cir. 2000)....................4, 5

Thompson v. Runnels,
705 F.3d 1089 (9th Cir. 2013)....................25

Timbs v. Indiana,
139 S. Ct. 682 (2019)....................32

United States v. Mackby,
261 F.3d 821 (9th Cir. 2001) 30, 33

W. Coast Truck Lines, Inc. v. Arcata Cmty. Recycling Ctr., Inc.,
846 F.2d 1239 (9th Cir. 1988) 13

Wash. State Grange v. Wash. State Republican Party,
552 U.S. 442 (2008) 8

Water-Pierce Oil Co. v. Texas,
212 U.S. 86 (1909) 32

Wolfson v. Brammer,
616 F.3d 1045 (9th Cir. 2010) 5

Younger v. Harris,
401 U.S. 37 (1971) 10

Statutes

35 U.S.C. § 261 20

Other Authorities

Hearing on AB 824 Before the Cal. Assembly Comm. on Health, 2019-20 Reg. Sess. (Mar. 26, 2019) 1, 18

Richard A. Posner, *Economic Analysis of Law* (4th ed. 1992) 23

INTRODUCTION

The statute the Attorney General describes bears little resemblance to the one the Legislature enacted. The Attorney General portrays AB 824 as merely adding new penalties to "conduct" that was "already unlawful." AG.Br.20. But text, structure, and history refute that mischaracterization of the statute. AB 824 extends far beyond preexisting state and federal law—and far beyond what the Constitution allows.

The legislators who drafted and voted for AB 824 were clear about its purpose: They wanted to "establish[] a *different standard of review* for pay-for-delay agreements than what was decided in the FTC v. Actavis case." *Hearing on AB 824 Before the Cal. Assembly Comm. on Health* at 7, 2019-20 Reg. Sess. (Mar. 26, 2019), https://bit.ly/31IfPiS ("*Hearing on AB 824*") (emphasis added). In other words, they wanted to make some patent settlements flunk scrutiny in California where they would otherwise pass. And they did. AB 824 not only erects a substantive standard far more restrictive than all others before it, but extends that uniquely restrictive standard to patent settlements completed wholly outside California. Compounding the injury, AB 824 subjects every person who assists in a patent settlement to multimillion-dollar penalties, even if the settlement was completed wholly in another state and even if it will *benefit* competition in the long-term.

Against that backdrop, AB 824 is unsustainable. It is a textbook example of a state law that violates the Commerce Clause by regulating commerce in other states. It is fundamentally at odds with federal patent law and the delicate balance the federal government has struck between innovation and competition. It imposes crippling monetary penalties not just on the companies that settle pharmaceutical patent litigation in violation of its terms, but on all their employees and agents who assist in a settlement effort—from the C-suite to the mailroom clerk who dispatches the signed papers. And it erects a veritable Matryoshka doll of presumptions that together make it all but impossible for defendants to prevail. In light of these constitutional infirmities and the concrete injuries AB 824 is *already* causing AAM's members, injunctive relief is plainly warranted. This Court should reverse.

ARGUMENT

I. AAM Is Likely To Succeed On The Merits.

A. AAM's "Pre-Enforcement" Commerce Clause Claim Is Ripe.

1. Although dressed in different constitutional garb, the Attorney General's standing (AG.Br.22-24) and constitutional ripeness (AG.Br.25-30) arguments are functionally identical. They lack merit regardless of their heading.

The Attorney General's top-line argument is that regulated entities cannot satisfy Article III in a "pre-enforcement" setting unless they unequivocally declare their intention to violate the law they seek to challenge. AG.Br.2, 19, 23, 24, 28-29. This is directly contrary to Supreme Court precedent. "Nothing in th[e Supreme]

Court's decisions requires a plaintiff who wishes to challenge the constitutionality of a law to confess that he will in fact violate that law." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 163 (2014). The Supreme Court has long adjudicated "pre-enforcement" challenges even absent a professed intent by the plaintiff to violate the challenged law, including outside the First Amendment context. *See, e.g.*, *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 540 (2012); *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 301-02 (1979); *Craig v. Boren*, 429 U.S. 190, 194-96 (1976).

The Attorney General's bottom-line argument is that, because he has not yet enforced AB 824 or clearly threatened to do so, AAM's claims must wait until another day. AG.Br.25-29. But the Attorney General refuses to disavow applying AB 824 to agreements completed wholly out of state, AG.Br.29, or to accept that the Constitution prohibits California from so applying its law, AG.Br.35-37, and those choices—by design—are upending AAM's members ability to conduct their affairs. The coercive force of AB 824 accordingly causes AAM's members economic harm regardless of whether the Attorney General ever brings an enforcement action. *See, e.g.*, *NIFLA v. Harris*, 839 F.3d 823, 833 (9th Cir. 2016) (pre-enforcement claim ripe where "[t]he AG … has not stated that she will not enforce the Act"), *adopted in relevant part and rev'd on other grounds*, 138 S. Ct. 2361, 2370 n.1 (2018); *LSO, Ltd. v. Stroh*, 205 F.3d 1146, 1154-55 (9th Cir. 2000) (similar); *Bland v. Fessler*, 88

F.3d 729, 737 (9th Cir. 1996) (similar). AAM's members' injuries are thus sufficiently concrete for Article III.

Nor do the factors applied in *Thomas v. Anchorage Equal Rights Commission*, 220 F.3d 1134 (9th Cir. 2000) (en banc), constitute "constitutional requirements" that must be satisfied in every case. AG.Br.26-28. The Attorney General stakes his ripeness arguments almost entirely on the three factors outlined in *Thomas*, but *Thomas* itself disavowed any intent to "establish a new" test for ripeness. 220 F.3d at 1137 n.1; AAM.Br.31. And this Court has repeatedly held that *Thomas* does not control when, as here, the challenged law is new (and thus there is no prosecution history), *see, e.g.*, *Wolfson v. Brammer*, 616 F.3d 1045, 1060 (9th Cir. 2010), or when, also as here, "tangible economic injury is alleged" based on the challenged law's coercive effect (in which case the plaintiffs' injuries are concrete regardless of whether the challenged law is enforced against them), *e.g.*, *Nat'l Audubon Soc'y, Inc. v. Davis*, 307 F.3d 835, 855 (9th Cir. 2002). *See* AAM.Br.31-32 (citing cases).

The Attorney General's attempt to distinguish these decisions plainly fails. His mischaracterization of *National Audubon Society* is particularly stunning. He suggests that case is off-point on the premise that the only "plaintiffs" there were "'bird-lovers'" who relied on aesthetic injury and were not "'potential violators'" of the statute they sought to challenge. AG.Br.27-28. But the Attorney General ignores the part of the decision AAM actually cited, in which this Court held that a *separate*

group of plaintiffs also had standing: "trappers" who sought to challenge a law that prohibited certain types of trapping. 307 F.3d at 854-55. The trappers obviously were "potential violators" of a law that restricted trapping, AG.Br.27-28, but this Court nonetheless held that it "need not rely on the three-factor test applied in *Thomas*" with respect to the trappers' claims, because "*the gravamen of the[ir] suit is economic injury rather than threatened prosecution*." 307 F.3d at 855 (emphasis in original). Based on that conclusion, this Court reversed the decision to dismiss the trappers' suit for lack of standing, holding that the trappers "satisf[ied] all three requirements of Article III standing," including "actual, discrete, and direct injury," even absent any specific threat of enforcement. *Id.* at 856.

The Attorney General ignores that holding, yet that holding dispels the claim that a risk of actual punishment is the only cognizable injury in a "pre-enforcement, as-applied challenge." AG.Br.28. The trappers in *National Audubon Society* chose to forbear from certain commercial activities "they would otherwise do" but for the new restrictive law. 307 F.3d at 856. So too here. Far from "conced[ing]" that they lack concrete injury, AG.Br.28, AAM's members have declared that, because of AB 824 and its massive penalties, they will be forced to suffer the substantial costs and risks of litigating patent suits to judgment "even if a procompetitive settlement agreement could otherwise be reached"—and that such forbearance from settling will cost them time and money, even if they are never penalized under AB 824.

Kuchii Decl. ¶6 (ER153); Khera Decl. ¶8 (ER148); Matsuk Decl. ¶6 (ER157).[1] As *National Audubon Society* makes clear, these economic harms are "directly traceable" to the "new[]" restrictive law that discourages plaintiffs from undertaking commercial activities. 307 F.3d at 855. Nothing more is required under Article III.

2. The prudential "'fitness' and 'hardship' factors are easily satisfied" too. *Susan B. Anthony List*, 573 U.S. at 167. First, AAM's challenge to AB 824 "presents an issue that is 'purely legal.'" *Id.* Either California possesses the never-before-heard-of authority to regulate agreements completed wholly out of state, or AB 824 violates the Commerce Clause. Likewise, either California may capsize the federally-drawn balance between competition and innovation, or AB 824 is preempted. These questions "will not be clarified by further factual development." *Id.*; *see, e.g.*, *Union Pac. R.R. Co. v. Cal. Pub. Utils. Comm'n*, 346 F.3d 851, 871-72 & n.22 (9th Cir. 2003) (Commerce Clause challenge to law not yet in effect ripe because the question is purely legal).

The Attorney General nonetheless insists "the Supreme Court has expressed disfavor with pre-enforcement, as-applied claims." AG.Br.29-30. But he again misreads the case law. In fact, the case he cites, *Washington State Grange v.*

[1] That forbearance is plainly a reasonable response to a law that was *expressly designed* to discourage a wide range of patent settlements by imposing more restrictive standards than existing federal or state law provide. *See* p.1, *supra*.

Washington State Republican Party, 552 U.S. 442 (2008), held that "*[f]acial* challenges are disfavored." 552 U.S. at 450 (emphasis added). There is no such "disfavor[]" for pre-enforcement *as-applied* challenges, which are common. *See, e.g.*, *Holder v. Humanitarian Law Project*, 561 U.S. 1, 15, 18, 25 (2010); *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 234, 249-53 (2010). And, as the Attorney General concedes, AG.Br.25 n.9, AAM's Commerce Clause claim challenges AB 824 *only as applied to settlements completed out of state*.

Second, "denying prompt judicial review would impose a substantial hardship on [AAM's members], forcing them to choose between refraining from" constitutionally protected activity or "risking costly [state-court] proceedings." *Susan B. Anthony List*, 573 U.S. at 167-68. No "assum[ptions]" are necessary to reach that conclusion. AG.Br.31. Nor is "speculation" required to recognize that AAM's members are engaged in the precise (constitutionally protected) conduct on which AB 824's sights are trained. AG.Br.23. All that is required is reading the statute and the declarations AAM submitted. *Every* settlement governed by AB 824 involves a generic or biosimilar company—AAM's membership. *See* §§ 134000(g) (ER96), 134002(a)(1) (ER98). The universe of brand-versus-generic/biosimilar patent litigation is massive and expanding. And, as the undisputed declarations make clear, AAM's members are at the center of it.

The declarations confirm that AAM's members are currently engaged in scores of brand-versus-generic/biosimilar patent suits across the country, and are currently being compelled to cease otherwise-lawful conduct because of AB 824's broad scope and crippling penalties. *See* AAM.Br.33 (citing declarations). Failing to address AAM's claims would thus leave AAM's members in the worst of all worlds: compelled to alter their nationwide conduct in response to the statute, but unable to challenge the statute's unconstitutional overreach. AAM's claims are plainly "suitable for judicial review." *Humanitarian Law Project*, 561 U.S. at 16.

That is particularly true given that AAM's claims arise under Section 1983, which is designed to give parties an opportunity to challenge unconstitutional state action in federal court without needing to exhaust state remedies. AAM.Br.37-38. The Attorney General brushes past the entire issue of federal abstention (AG.Br.51) without seriously disputing that federal courts will dismiss any challenge to AB 824 under *Younger v. Harris*, 401 U.S. 37 (1971), once he initiates state-court proceedings under the statute. Indeed, the Attorney General blithely insists that it is too early to bring a Section 1983 challenge to AB 824 because he has not yet initiated any enforcement actions under it—but, once he does so, he undoubtedly will turn around and argue under *Younger* that it is too late for federal intervention. The case law does not countenance this anomalous result. To the contrary, the precedents AAM addressed in its opening brief (AAM.Br.36-37 & n.5), but which the Attorney

General disregards, confirm that this Court has the power, and therefore the duty, to adjudicate AAM's claims now.

B. AB 824 Violates the Commerce Clause As Applied To Settlements Completed Wholly Out of State.

The Commerce Clause "precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State." *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989) (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality op.)). If a transaction takes place in State *A*, it is beyond "the inherent limits of [State *B*'s] authority"—full stop. *Id.* AB 824 violates this bedrock rule of constitutional law.

1. The Attorney General's contrary position mischaracterizes the statute. The Attorney General claims that AB 824 regulates not "discrete transactions," but "practice[s]" that "delay … generic competition in California's pharmaceuticals market." AG.Br.35-36. That is simply false. AB 824 applies to one thing only: "agreement[s] resolving or settling … patent infringement claim[s]"—*i.e.*, patent settlements—each of which is a single, discrete transaction. § 134002(a)(1) (ER98).

The dispositive question, therefore, is whether AB 824 applies to *patent settlements* negotiated, written, agreed upon, signed, and entered wholly outside California. AB 824's text and structure provide an unequivocal answer—yes.

None of AB 824's operative provisions contains any limitation on the statute's application to patent settlements completed wholly out of state. Neither do its $20-

million penalty provisions, § 134002(e)(1)(A)(i)-(ii). The closest thing to a state nexus the Attorney General can point to is the provision setting the upper limit for penalties *above* the $20-million mandatory minimum. § 134002(e)(1)(A)(iii) (ER100). But the Attorney General elides the fact that AB 824 unambiguously imposes a minimum $20-million penalty *without regard to whether the offending settlement agreement has any California nexus or impact*. § 134002(e)(1)(A)(i)-(ii) (ER100). And AB 824 does not otherwise limit its substantive restrictions on patent settlements to those with a California nexus. *See* § 134002(a)-(b) (ER98-99). Far from demonstrating a limit on AB 824's reach, the "plain language of the statute" (AG.Br.33) thus confirms the opposite: AB 824 applies to settlements completed wholly outside California. AAM.Br.25-26.

That is not just because the statute lacks "an express territorial restriction." AG.Br.37. Many state laws can reasonably be read to apply only to in-state conduct, despite lacking "an express territorial restriction." But AB 824 is not among them. AB 824's drafters knew how to limit certain aspects of the statute to California—yet they chose to use the boundaries of California only as an upper limit on penalties, not to delineate the scope of conduct to which the statute applies. In light of that text and structure, the only reasonable reading of AB 824 is that it "appl[ies] to" settlements completed "wholly outside California." AG.Br.37; *see W. Coast Truck Lines, Inc. v. Arcata Cmty. Recycling Ctr., Inc.*, 846 F.2d 1239, 1244 (9th Cir. 1988)

("When some statutory provisions expressly mention a requirement, the omission of that requirement from other statutory provisions implies that [the legislature] intended both the inclusion of the requirement *and* the exclusion of the requirement."); *accord People v. Steward*, 228 Cal. Rptr. 3d 877, 883, 886 (Cal. Ct. App. 2018) (same under California law).

That is why the Attorney General's "canons of construction" argument fails. *See* AG.Br.34. A statute may receive a limiting construction only when it is "readily susceptible" of that alternative reading. *Rosenblatt v. City of Santa Monica*, 940 F.3d 439, 447 (9th Cir. 2019). But the Attorney General never argues that AB 824 can be construed to apply only to agreements completed in California—because it cannot.[2] The Attorney General's proposed construction does nothing to avoid the constitutional problem, since he plainly contemplates that AB 824 applies to wholly out-of-state settlements as long as they have some downstream impact on the California market. AG.Br.34. As explained below, that *undisputed* application of AB 824 is exactly what violates the Commerce Clause.

[2] To be sure, if this Court were to conclude in a published opinion that AB 824 should be construed, as a matter of constitutional avoidance, not to apply to settlements completed wholly outside California, that holding would provide meaningful relief. But at the point where this Court feels compelled to effectively rewrite the law in order to salvage it from constitutional demise, AAM respectfully submits that the more straightforward course would be to hold that AB 824 is unconstitutional vis-à-vis settlements completed wholly outside California.

2. The Attorney General fundamentally misunderstands what the Commerce Clause prohibits. What matters is *not* whether the transaction a state seeks to regulate will eventually have effects within that state, or even whether the goods at issue may one day be resold in that state at prices the state dislikes. Rather, "[t]he critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State." *Healy*, 491 U.S. at 336. If the answer to that question is yes, the regulation is per se invalid to that extent, *regardless* of any eventual in-state effects or nexuses. *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986); *Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608, 615-16 (9th Cir. 2018) (invalidating a California statute as applied to "transactions that occur wholly outside of the State," even though the products covered in the transactions were produced in California by Californians); *Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1322-24 (9th Cir. 2015) (en banc) ("easily conclud[ing]" that a California statute was unconstitutional as applied to "a transaction that occurs wholly outside the State," even though one of the parties to the transaction was a California resident and even though some of the funds the statute raised were set to go into a California-controlled account).[3]

[3] The Attorney General tries to explain away these adverse decisions with a conclusory assertion that this Court analyzed constitutionality "in a fact-specific, as-applied context." AG.Br.37. But the "fact" that mattered in those cases was that the

That is why AB 824 is not remotely similar to "the law upheld in *Walsh*." AG.Br.33 (citing *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003)). There, a Maine law established a mechanism through which manufacturers that sold prescription drugs in Maine could negotiate a rebate for Maine's elderly low-cost-drug program; if a manufacturer refused to agree to a rebate, Maine would impose prior-authorization requirements on certain in-state sales of the manufacturer's medicines. 538 U.S. at 654-55. The statute did *not* "regulate[] a stream of commerce in pharmaceuticals that extended into Maine." AG.Br.36. All it regulated were transactions *completed entirely in Maine*. 538 U.S. at 669 (concluding that the statute "does not regulate … any out-of-state transaction").

In contrast, AB 824 applies to agreements completed wholly outside California as long as any products covered therein are later sold in the state (even if not by a party thereto). The same was true of a separate Maine statute that the district court *invalidated* in the *Walsh* litigation and that the state did not defend on appeal. *See Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 72 n.2, 81-82 n.10 (1st Cir. 2001). Again, AB 824 regulates patent settlements and patent settlements alone. *See* § 134002(a)(1) (ER98). Like most complex commercial agreements, patent settlements are negotiated, written, renegotiated, rewritten, agreed upon,

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state law at issue applied to conduct wholly outside the state's boundaries. The same is true of AB 824. *See supra*. The same fate should befall it.

finalized, and then signed, at which point they are implemented through a court filing. If all those steps take place wholly outside California, then AB 824 cannot constitutionally be applied to that settlement—"*whether or not [that settlement] has effects within the State*." *Healy*, 491 U.S. at 336 (emphasis added; citation omitted); *accord Daniels Sharpsmart*, 889 F.3d at 615 ("The mere fact that some nexus to a state exists will not justify regulation of wholly out-of-state transactions."); *see also, e.g.*, *Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 667-72 (4th Cir. 2018) (invalidating state law that regulated wholly out-of-state transactions, even though it was triggered by in-state sales); *Pharm. Research & Mfrs. of Am. v. D.C.*, 406 F. Supp. 2d 56, 68-71 (D.D.C. 2005) (same).

That has been the law for nearly a century. The Supreme Court held in *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935), that a New York law violated the dormant Commerce Clause as applied to a transaction that took place in Vermont, even though (1) all of the milk sold in the Vermont transaction was destined for resale in New York, (2) the Vermont buyer and the New York reseller were the same company, and (3) the Vermont transaction undoubtedly affected the prices New Yorkers would pay for milk. *Id.* at 518-21. Notwithstanding the in-state effects of that out-of-state transaction (and the fact that it could be characterized as part of a "practice" of affecting milk prices *in New York*), the Court held that the New York

statute could not constitutionally apply to the transaction for a simple reason: It took place wholly outside New York. *Id.* at 521.

The Attorney General nonetheless argues that "any state can apply its antitrust law to redress or punish" "an agreement or conspiracy to engage in anti-competitive conduct" *regardless of where that agreement takes place*, "so long as the anti-competitive conduct extends into that state." AG.Br.34-35. That is plainly not the law, *see, e.g.*, *In re Lorazepam & Clorazepate Antitrust Litig.*, 295 F. Supp. 2d 30, 47-48 (D.D.C. 2003) (invalidating application of "the Illinois Antitrust Act [to] Sales that Occurred in Texas and New Mexico"), which explains why none of the federal cases the Attorney General cites supports the proposition. "The conduct complained of" in *Knevelbaard Dairies v. Kraft Foods, Inc.*, 232 F.3d 979 (9th Cir. 2000), "took place not only in Wisconsin, where [part of the conspiracy] was located, *but in California" as well*. *Id.* at 993-94 (emphasis added). "That being so, California [could] apply its antitrust and unfair competition statutes consistent with the Commerce Clause." *Id.* at 994. Of course it could. The Commerce Clause does not bar states from regulating agreements that take place partly-but-not-entirely within their borders; only "transactions completed *wholly out of state*" are off-limits. *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1102-03 (9th Cir. 2013) (emphasis added). For this reason, the assertion that AAM's position would call into question numerous state-law antitrust claims, AG.Br.36, is unfounded.

The Seventh Circuit's decision in *In re Brand Name Prescription Drugs*—the only other federal decision the Attorney General cites—also does not support the Attorney General's newfangled antitrust exception to the Commerce Clause. The court there recognized that "Alabama antitrust law" could *not* "constitutional[ly]" be applied to "sales from plants or offices in other states to pharmacies in other states." 123 F.3d 599, 613 (7th Cir. 1997). To be sure, the court suggested in dicta that Alabama law could apply to sales made to Alabama pharmacies at prices that were inflated by an alleged price-fixing scheme. *Id.* But that observation is irrelevant here; AB 824 imposes sanctions on discrete out-of-state transactions among non-Californians, based merely on those transactions' *potential* effects in California.

To approve the Attorney General's attempt to police wholly out-of-state settlement agreements would allow a single state to wreak havoc on interstate commerce—which is exactly what the Constitution is designed to prevent. *Healy*, 491 U.S. at 336-37. If the Attorney General were right, then California could impose California law on settlements completed in New Jersey, even if they were fully lawful under New Jersey (and federal) law. Worse, New Jersey could turn around and do the same thing.[4] The Commerce Clause must be applied to "protect[]

[4] Absent judicial intervention, that outcome is looking increasingly likely. As of the date of this filing, five states have proposed bills that follow California's lead by imposing new state-law standards to evaluate patent settlements. *See, e.g.*, Ill. House

against" such inconsistent legislation arising from the projection of one statue regulatory regime into the jurisdiction of another state." *Id.*

In the end, the Attorney General is right about one thing: "In the modern era, the Supreme Court has rarely held that statutes violate the extraterritoriality doctrine." AG.Br.33 (quoting *Rocky Mountain Farmers Union*, 730 F.3d at 1101). But that is not because the Supreme Court has abandoned the dormant Commerce Clause.[5] It is because most states have gotten the message that the Constitution forbids them from regulating transactions completed wholly in other states, even if the transactions will have downstream effects within their borders. *Healy*, 491 U.S. at 336. It is time California got the message too. Regardless of whether the state law at issue is a price-affirmation law, *Brown-Forman*, 476 U.S. at 579, a price-control law, *Frosh*, 887 F.3d at 667-71, an anti-takeover law, *Edgar*, 457 U.S. at 642-43 (plurality op.), or an antitrust law, the dormant Commerce Clause prohibits states from regulating wholly out-of-state "agreement[s]," including those that have effects "in[] th[e] state." AG.Br.34-35.

Bill 4822 (introduced Feb. 11 2020); Conn. Raised Bill No. 251 (introduced Feb. Session 2020); N.Y. Senate Bill 5169 (originally proposed Apr. 12, 2019).

[5] Quite the opposite. *See generally Tenn. Wine & Spirits Retailers Ass'n v. Thomas*, 139 S. Ct. 2449 (2019).

C. AB 824 Is Preempted.

1. The Attorney General does not meaningfully respond to the argument that AB 824 "upset[s] the careful balance" between federal patent and antitrust policies. *Edgar*, 457 U.S. at 634; *see* AAM.Br.39-45. Instead, he argues that "federal antitrust law" does not itself preempt "California law." AG.Br.42. That is true—but irrelevant. As this Court held in *Morseburg v. Balyon*, even state laws aimed at protecting "competition" are "preempted by the federal patent law" when, as here, they "upset the federally struck balance" between competition and innovation. 621 F.2d 972, 977 (9th Cir. 1980). This argument was front-and-center in AAM's opening brief. *See, e.g.*, AAM.Br.5, 42-45. Yet the Attorney General ignores it.

Nor can the Attorney General meaningfully dispute that AB 824 adopts a radically different standard of review than the Supreme Court prescribed in *Actavis*. AB 824's drafters made clear that they wanted to "establish[] a different standard of review for pay-for-delay agreements than … [*Actavis*]." *Hearing on AB 824*, at 7. Consistent with that intent, AB 824 erects the very presumption of illegality *Actavis* rejected, adopts a form of streamlined antitrust review *Actavis* also rejected, shifts the burden from the plaintiff to the defendant, limits available defenses, and expands the universe of settlements subject to antitrust liability in the first place. *See* AAM.Br.41-42.

The Attorney General claims that *Actavis* should not be read as holding that "a 'large' and 'unjustified' payment" is necessary for antitrust review. AG.Br.42-43. But even if the Attorney General were right on those issues,[6] that would not save the statute, because the fundamental points remain: First, state laws that upset the federal balance between competition and innovation are preempted. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989). Second, patent litigation is not "'a field which the States have traditionally occupied,'" so "no presumption against preemption applies." *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1326-27 (Fed. Cir. 2017) (quoting *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 347 (2001)). Third, *Actavis* determined the permissible scope of antitrust scrutiny of patent settlements with explicit reference to the balance between "patent and antitrust policies." *FTC v. Actavis, Inc.*, 570 U.S. 136, 148 (2013). And, fourth, AB 824 self-consciously strikes a different balance between those competing objectives than federal law. AB 824 therefore is preempted. AAM.Br.41-42; *see also In re Cipro Cases I & II*, 348 P.3d 845, 859 (Cal. 2015) ("The United States Supreme Court is the final arbiter of … the extent to which interpretations of

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[6] He is not. Every circuit to confront the issue has concluded that *Actavis* requires plaintiffs to "allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment." *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 251-52 (3d Cir. 2017) (quoting *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 552 (1st Cir. 2016)).

antitrust law—whether state or federal—must accommodate patent law's requirements….").

2. The Attorney General charges AAM with having "forfeited" the argument that AB 824 conflicts with section 282 of the Patent Act. AG.Br.39; *see* 35 U.S.C. § 282(a) ("A patent shall be presumed valid."). But AAM has argued that AB 824 conflicts with the Patent Act from the outset, *see, e.g.*, ER81 ¶87, ER83 ¶90 (highlighting the conflict), and litigants are not precluded from advancing new authorities on appeal in support of arguments raised below. *See Thompson v. Runnels*, 705 F.3d 1089, 1098 (9th Cir. 2013) (collecting cases).

The Attorney General's attempts to engage with the merits of AAM's preemption arguments fare no better. Whereas the Patent Act expressly grants patent holders the right to convey exclusive licenses, 35 U.S.C. § 261, AB 824 defines "anything of value" specifically to "includ[e]" "an exclusive license," § 134002(a)(1)(A) (ER98). And nothing in the statute supports the assertion that "AB 824 does not reach exclusive licenses unless the license is being given to induce a rival to agree not to compete," AG.Br.40, which is likely why the Attorney General cites nothing to support it. Under AB 824, a settlement in which the only terms are that the generic may enter the market in nine months with "an exclusive license" is presumptively unlawful (because it conveys something of value and "limit[s] … sales … for a[] period of time," § 134002(a)(1)(B) (ER98)), even if the

agreement enabled earlier generic competition. By treating a patentee's mere exercise of its federal right under section 261 to make a license exclusive as *presumptively illegal*, AB 824 clearly conflicts with federal law.

As for section 282(a), the Attorney General insists that AB 824's prohibition on presuming "[t]hat any patent is enforceable," § 134002(b)(2) (ER99), is consistent with the Patent Act because "validity" (which section 282(a) requires courts to "presume[]") and "enforceability" (which AB 824 prohibits courts from presuming) are not the same. AG.Br.40. The Attorney General offers little support for his surprising suggestion that AB 824 § 134002(b)(2) only means to refer to technical enforceability (*i.e.*, "whether the patent was procured by fraud or wrong doing"). *Id*. If the Attorney General really means to argue that the patents at issue in a settlement may be presumed valid (*i.e.*, novel, nonobvious, and the like) under AB 824, then he should be estopped from trying to take back that concession in any subsequent enforcement action.

In any event, § 134002(b)(2) *still* upsets the federal balance even under the Attorney General's narrow reading. The Supreme Court held in *Buckman* that state-law "fraud-on-the-FDA claims" were "impliedly pre-empted by[] federal law" because "allowing" such state-law claims could "skew[]" the "delicate balance of statutory objectives" that the federal government sought to maintain. 531 U.S. at 348; *see* AAM.Br.43-44. The same reasoning applies here, where California is

assuming the prerogative to police fraud against the Patent Office by foreclosing a presumption of validity *and* enforceability that would apply under federal law. *See, e.g., Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1352, 1357-59 (Fed. Cir. 2013).

3. Finally, the Hatch-Waxman Act preempts AB 824 because the latter will cause pharmaceutical companies to bring fewer generic products to market. AAM's members—the targets of the statute—have submitted sworn declarations confirming that AB 824 will "make it difficult, if not impossible," for generic manufacturers "to settle" patent litigation, Ragan Decl. ¶10 (ER162-63); *accord, e.g.*, Matsuk Decl. ¶6 (ER157); Silhavy Decl. ¶5 (ER166), which in turn will cause them to "bring fewer generic … products to market," Wilson Decl. ¶11 (ER173); *accord, e.g.*, Matsuk Decl. ¶¶7-11 (ER157-58); Silhavy Decl. ¶5 (ER166), because patent settlements are the principal mechanism by which generic medicines have typically been able to enter the market before patent expiry. AAM.Br.47-48. Far from "baseless factual assertions," AG.Br.48, these sworn declarations form the only evidence in the record about the statute's practical effects.

The declarations also confirm basic economics and common sense. AB 824 inverts the burden of proof and thus makes the standard of review more favorable to the party challenging a patent settlement as allegedly anticompetitive. *See* AG.Br.48. That makes it more likely that patent settlements will be challenged, and

more difficult for settling parties to defend themselves. AB 824 also imposes penalties above what were previously available under state and federal law, which makes losing a challenge far more costly. Add it all up and AB 824 increases the expected cost of settling a patent suit, which in turn will decrease the incidence of settlement—which is the whole point of the statute—thereby inhibiting the flow of generic medicines onto the market. *Cf. Amgen*, 877 F.3d at 1329 (concluding that subjecting biosimilar manufacturers to "'the shadow of 50 States' tort regimes,' and unfair competition standards, could 'dramatically increase the burdens' on [them] beyond those contemplated by Congress" (quoting *Buckman*, 531 U.S. at 350)).

The Attorney General's sole response is that AB 824 does not actually "prevent[] companies from launching new drugs" or outlaw "agreements where there [are] no rival payments." AG.Br.48-49. But a law need not *forbid* certain transactions to make them costlier. And a law that makes it costlier to launch new drugs will inevitably diminish the number of new drugs that manufacturers launch. *See* Richard A. Posner, *Economic Analysis of Law* 5 (4th ed. 1992). Because that is exactly what it will do, AB 824 is fundamentally at odds with the basic purposes of the Hatch-Waxman Act, and thus preempted on that basis as well.

D. AB 824 Violates the Excessive Fines Clause.

A $20-million mandatory-*minimum* penalty is unconstitutionally excessive vis-à-vis any "person" such as an employee or agent who merely "assists" in settling

a pharmaceutical patent suit and who derives no value therefrom. § 134002(e)(1)(A) (ER100). That should not be a controversial proposition. Yet the Attorney General fights tooth-and-nail to keep this Court from addressing it. His efforts at evasion lack merit.

At the outset, the Attorney General claims that "a concrete scenario" is required to decide this claim. AG.Br.51. But the only "concrete scenario" he offers is one in a state court has ordered that an individual agent or employee pay penalties of at least $20 million under AB 824. No case-specific facts are needed to recognize that such an application of the statute is plainly unconstitutional. *See* AAM.Br.50-51. Levying a $20-million penalty on an employee of a generic drug manufacturer (whether a secretary or an in-house lawyer) would be sentencing that employee to financial ruin—condemning her to all-but-certain bankruptcy all for having committed the "offense" of simply doing her job. *See United States v. Mackby*, 261 F.3d 821, 829 (9th Cir. 2001) (penalty violates Eighth Amendment if "grossly disproportionate" to putative "offense"). Nor are additional facts necessary to realize that waiting for this "scenario" to materialize would block individuals from accessing the federal courts. The Attorney General does not meaningfully dispute that, under *Younger*, no federal Section 1983 challenge could be brought once a state enforcement action is under way—much less after a fine is imposed.

As for the merits, the Attorney General's attempts to defend AB 824's extraordinary penalty on individuals without any regard to fault are belied by the statute's text and structure. AB 824 very much *does* "reach agreements that cause no harm to consumers." AG.Br.53. It presumes that all patent settlements that allow a generic to enter the market with a time-limited "exclusive license" are anticompetitive and unlawful—even if they allow generic entry years prior to patent expiry—unless they allow for *immediate* entry. § 134002(a)(1) (ER98). AB 824 thus presumes *anticompetitive* settlements the FTC has concluded are *procompetitive*. *See* AAM.Br.45 (citing FTC brief). And, *contra* AG.Br.53, AB 824's penalty provisions are not limited to "only those agreements" that "harm consumers." To take just one example, a pharmaceutical patent settlement that leaves consumers no worse off than they would have been without it (*i.e.*, in which the benefits and burdens are in equipoise) not only violates AB 824, but triggers its $20-million-minimum-per-person penalties. *See* § 134002(a)-(b) (ER98-99).

Nor are AB 824's penalty provisions remotely similar to other state or federal laws. *None* of the statutes the Attorney General discusses (AG.Br.53-54) authorizes *any* penalties against natural persons who merely assist in and derive no benefit from a violation, let alone minimum penalties of $20 million. The Attorney General's sole remaining argument it is that it is not necessarily excessive to force someone

who merely assisted in a patent settlement to pay *at least* a $20-million penalty. AG.Br.54. To state that argument is to refute it.

Finally, the Attorney General contends that federal courts "must defer to state legislatures about appropriate penalties for state offenses," and thus cannot "'interfere with [such legislation]'" except to the extent the fines they impose "amount to a deprivation of property without due process of law.'" AG.Br.50, 52 (quoting *Water-Pierce Oil Co. v. Texas*, 212 U.S. 86, 111 (1909)). Notably, however, the main case the Attorney General cites in support of that proposition expressly relied on the fact "that the prohibition of the 8th Amendment to the Federal Constitution against excessive fines" did not apply to "legislation of the states." *Water-Pierce Oil*, 212 U.S. at 111. And the Supreme Court held *just last year* that the Excessive Fines Clause is incorporated against the states in *Timbs v. Indiana*, 139 S. Ct. 682 (2019)—a decision the Attorney General fails to acknowledge. Following *Timbs*, AB 824's penalty is obviously unconstitutional vis-à-vis individuals who merely assist with executing patent settlements, because it is "grossly disproportionate" to their putative "offense." *Mackby*, 261 F.3d at 829.

E. AB 824 Violates Due Process.

AB 824 stacks the deck against defendants. It "presume[s]" that run-of-the-mill patent settlements are anticompetitive and unlawful, § 134002(a)(1) (ER98), and makes it nearly impossible to rebut that threshold presumption. Given that

patent settlements take years to complete even if they permit pre-patent-expiry generic entry, few defendants will be able to show that a challenged settlement *already* has had procompetitive effects. § 134002(a)(3)(B) (ER99). But, even if a defendant proves that the settlement "*will* have procompetitive effects" once the generic enters the market *and* that those long-term benefits will outweigh the short-term status quo, that *still* does not "suffic[e] to rebut [AB 824's] presumption" of anticompetitiveness, as the district court recognized. ER21 (emphasis in original).

The Attorney General sees nothing wrong with forcing defendants to do the impossible. Indeed, the Attorney General contends that, because AB 824 does not completely prevent defendants from putting on a defense, it must be consistent with due process. AG.Br.54-56. That is not the law. A presumption that appears on paper to allow a meaningful opportunity to rebut it still violates due process if, in practice, it operates as a conclusive determination of liability—particularly when (as here) liability comes with huge penalties. *Speiser v. Randall*, 357 U.S. 513, 524 (1958).

Nor is AB 824 on par with "established antitrust jurisprudence." AG.Br.56. Established law requires "the reasonableness of agreements under the antitrust laws … to be judged at the time the agreements are entered into." *Id.* (citation omitted). But it has never been the law that a court judging the reasonableness of an agreement must ignore procompetitive benefits that *will* result, and *will* outweigh any short-term consequences, simply because those expected benefits are still to

come. Not only does the government bear the ultimate burden under every "established" antitrust standard, but defendants under "established" standards may shift the burden back by showing that, "as of the time the[agreement was] made," the settlement *will* have benefits once the generic enters the market that *will* render it procompetitive in the long run. *Cipro*, 348 P.3d at 870. Because AB 824 precludes defendants from relying on such future benefits, its presumption of illegality becomes effectively irrebuttable, in violation of due process.

II. AAM Satisfied The Remaining Preliminary-Injunction Factors.

The Attorney General's repeated efforts to downplay AB 824's consequences and to ignore AAM's members' declarations cannot obscure the basic reality: AB 824 is causing AAM's members economic and constitutional injuries *today*, and those injuries are, and will continue to be, irreparable as a matter of fact and law. Indeed, the Attorney General does not dispute that constitutional injury is irreparable as a matter of law; his only argument falls back on the merits. AG.Br.58-59. So, even putting aside the Eleventh Amendment—which precludes AAM's members from recouping any money they spend or lose due to AB 824, but which the Attorney General casually overlooks—irreparable injury necessarily follows if this Court concludes that AAM is likely to succeed on any of its claims.

The balance of equities also favor injunctive relief. The Attorney General suggests that an order precluding it from enforcing an unconstitutional law causes

"irreparable injury" even greater than AAM's members'. AG.Br.60 (quoting *Maryland v. King*, 567 U.S. 1301, 1301 (2012) (Roberts, C.J., in chambers)).[7] But a state "is in no way harmed by issuance of an injunction that prevents the state from enforcing *unconstitutional* restrictions." *Legend Night Club v. Miller*, 637 F.3d 291, 302-03 (4th Cir. 2011) (emphasis added); *see also Melendres v. Arpaio*, 695 F.3d 990, 1002 (9th Cir. 2012). And California has no cognizable interest in regulating commerce in other states, or in striking a balance between competition and innovation different from the federal government's—whether or not it has done so through "representatives of its people." AG.Br.60.

Finally, AB 824 is contrary to the public interest. Many brand-versus-generic/biosimilar patent cases that "do not settle" result in judgment *for the brand-name drug company*. AG.Br.9. Very often, then, not settling means no generic or biosimilar competition, and no price savings for patients, for years until patents expire. Nor is challenging-patents-but-not-settling-infringement-cases a viable long-term strategy. Patent litigation in this context is extraordinarily expensive; few generic and biosimilar manufacturers are able to spend millions of dollars litigating every patent blocking their entry. AAM.Br.10-12. In sum, AB 824 will frustrate

[7] *King* is completely inapposite. That single-Justice, in-chambers opinion—which merely stayed an appellate-court decision that had overturned a rape conviction—did not address the standard for enjoining a state from enforcing a law that is likely unconstitutional and causing irreparable injury. 567 U.S. at 1301.

generic and biosimilar entry, diminish competition, and raise prescription-drug prices for patients, taxpayers, and others who pay for health care—and therefore harm the very public the statute was designed to help.

CONCLUSION

For the reasons set forth above, this Court should reverse.

Respectfully submitted,

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March 19, 2020

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Circuit R. 32-1(b) because this brief contains 6,998 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. 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 in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman type.

March 19, 2020

s/Jay P. Lefkowitz, P.C.
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CERTIFICATE OF SERVICE

I hereby certify that on March 19, 2020, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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