UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA

ASSOCIATION FOR ACCESSIBLE MEDICINES, Plaintiff, - against - XAVIER BECERRA, in his official capacity as Attorney General of the State of California, Defendant.	Case No. **PLAINTIFF'S NOTICE AND MOTION FOR PRELIMINARY INJUNCTION**

Pursuant to Federal Rule of Civil Procedure 65(a) and the Local Rules of the Eastern District of California, Plaintiff Association for Accessible Medicines ("AAM"), on behalf of itself and its members, hereby moves this Court for an order granting its Motion for Preliminary Injunction and thereby barring Xavier Becerra, in his official capacity as Attorney General of the State of California (the "Attorney General"), as well as the Attorney General's officers, agents, employees, attorneys, and all persons in active concert or participation with them who receive actual notice of the Order, from implementing or enforcing AB 824 against AAM, its member companies, or their agents and licensees.

This Motion is based upon all the files, records, and proceedings herein, including the accompanying memorandum of law and supporting declarations, as

well as any evidence that may be submitted at the hearing on the motion. As discussed in the accompanying memorandum: (1) AAM is likely to succeed on the merits of its claims for declaratory and injunctive relief; (2) AAM and its members will suffer irreparable injury if the Attorney General is not enjoined from implementing and enforcing AB 824; (3) granting the requested injunction will not substantially harm the Attorney General, so the balance of hardships favors AAM and its members; and (4) granting the injunction will further the public interest.

AAM requests that the Court require no security, or minimal security at most, because the Attorney General will suffer no injury from the issuance of a preliminary injunction.

Dated: November 12, 2019

KIRKLAND & ELLIS LLP

/s/ Matthew D. Rowen

Matthew D. Rowen
(CA Bar 292292)
1301 Pennsylvania Avenue NW
Washington, DC 20004
(202) 389-5000
matthew.rowen@kirkland.com

Jay P. Lefkowitz, P.C.
(*pro hac vice forthcoming)*
601 Lexington Avenue
New York, NY 10022
(212) 446-4800
lefkowitz@kirkland.com

Attorneys for
Association for Accessible Medicines

CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of November, 2019, I electronically filed the foregoing Plaintiff's Notice and Motion for Preliminary Injunction with the Clerk of the Court for the United States District Court for the Eastern District of California using the CM/ECF system. This document has been served by hand to the following:

Counsel for Defendant Attorney General Xavier Becerra
Office of the Attorney General
1300 I Street
Sacramento, CA 95814-2919
(916) 445-9555

xavier.becerra@doj.ca.gov

/s/ Matthew D. Rowen
Matthew D. Rowen

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA

ASSOCIATION FOR ACCESSIBLE MEDICINES, Plaintiff, - against - XAVIER BECERRA, in his official capacity as Attorney General of the State of California, Defendant.	Case No.

MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

TABLE OF CONTENTS

INTRODUCTION 1

STATEMENT OF FACTS 8

A. Patent Settlements Save Americans Billions of Dollars in Healthcare Costs Every Year 8

B. The Supreme Court Confirms that Most Patent Settlements Are Procompetitive and Lawful 11

C. California Enacts Assembly Bill 824 13

JURISDICTION 17

ARGUMENT 17

I. AAM IS LIKELY TO SUCCEED ON THE MERITS 18

A. AB 824 Directly Regulates Transactions that Take Place in Other States and Therefore Violates the Commerce Clause 18

B. AB 824 Upsets the Delicate Federal Balance Between Competition and Innovation, and Is Therefore Preempted 27

C. AB 824's Exorbitant Monetary Penalties Violate the Eighth Amendment Prohibition on Excessive Fines 39

D. AB 824's Burden-Shifting Regime Violates AAM's Members Procedural Due Process Rights 44

II. AAM'S MEMBERS WILL SUFFER IRREPARABLE HARM ABSENT AN INJUNCTION 46

III. THE BALANCE OF HARDSHIPS AND PUBLIC INTEREST FAVOR THE INJUNCTION 51

CONCLUSION 54

TABLE OF AUTHORITIES

Cases

Allergan, Inc. v. Athena Cosmetics, Inc.,
738 F.3d 1350 (Fed. Cir. 2013) 21

Am. Libraries Ass'n v. Pataki,
969 F. Supp. 160 (S.D.N.Y. 1997) 50

Am., Inc. v. Skechers USA, Inc.,
890 F.3d 747 (9th Cir. 2018) 47

Andrx Pharm., Inc. v. Biovail Corp. Int'l,
256 F.3d 799 (D.C. Cir. 2001).....29

Apani Sw., Inc. v. Coca-Cola Enters., Inc.,
300 F.3d 620 (5th Cir. 2002) 37

Arizona v. United States,
567 U.S. 387 (2012).....28

Armstrong v. Exceptional Child Ctr., Inc.,
135 S. Ct. 1378 (2015).....28

Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris,
729 F.3d 937 (9th Cir. 2013) 23

Ass'n for Accessible Med. v. Frosh,
887 F.3d 664 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019) 22

Ass'n for Molecular Pathology v. Myriad Genetics, Inc.,
569 U.S. 576 (2013).....5, 32

Austin v. United States,
509 U.S. 602 (1993).....38

Baldwin v. G.A.F. Seelig, Inc.,
294 U.S. 511 (1935).....19, 20

Biotechnology Indus. Org. v. District of Columbia,
496 F.3d 1362 (Fed. Cir. 2007) 32

BMW of N. Am., Inc. v. Gore,
517 U.S. 559 (1996).....18

Bonito Boats, Inc. v. Thunder Craft Boats, Inc.,
489 U.S. 141 (1989).....28, 38

Brown Shoe Co. v. United States,
370 U.S. 294 (1962).....36, 46

Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.,
476 U.S. 573 (1986).....18, 19, 23

Buckman Co. v. Pls.' Legal Comm.,
531 U.S. 341 (2001).....35

Cal. Dental Ass'n v. FTC,
526 U.S. 756 (1999).....37

California v. ARC Am. Corp.,
490 U.S. 93 (1989).....27

Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S,
566 U.S. 399 (2012).....3, 8, 9, 22

Carolina Trucks & Equip., Inc. v. Volvo Trucks of N. Am., Inc.,
492 F.3d 484 (4th Cir. 2007) 19

Chamber of Commerce of the U.S. v. Edmondson,
594 F.3d 742 (10th Cir. 2010) 48

Chinatown Neighborhood Ass'n v. Harris,
794 F.3d 1136 (9th Cir. 2015) 23

In re Cipro Cases I & II,
348 P.3d 845 (Cal. 2015).....28, 52

City of Burbank v. Lockheed Air Terminal Inc.,
411 U.S. 624 (1973).....35

Comm'ns Imp. Exp. S.A. v. Republic of the Congo,
757 F.3d 321 (D.C. Cir. 2014).....29

Connell Constr. Co. v. Plumbers & Steamfitters Local Union No. 100,
421 U.S. 616 (1975).....27

Copperweld Corp. v. Indep. Tube Corp.,
467 U.S. 752 (1984).....12

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

Davis v. District of Columbia,
158 F.3d 1342 (D.C. Cir. 1998).....49

Dean Foods Co. v. Brancel,
187 F.3d 609 (7th Cir. 1999) 19

Deja Vu of Nashville, Inc. v.
Metro. Gov't of Nashville & Davidson Cty.,
274 F.3d 377 (6th Cir. 2001) 52

Elrod v. Burns,
427 U.S. 347 (1976).....49

Farina v. Nokia Inc.,
625 F.3d 97 (3d Cir. 2010) 5, 28, 35

Fed. Trade Comm'n v. AbbVie Inc.,
329 F. Supp. 3d 98 (E.D. Pa. 2018).....36

Frew ex rel. Frew v. Hawkins,
540 U.S. 431 (2004).....48

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

Geier v. Am. Honda Motor Co.,
529 U.S. 861 (2000).....4

Gen. Talking Pictures Corp. v. W. Elec. Co.,
305 U.S. 124 (1938).....35

Gordon v. Holder,
721 F.3d 638 (D.C. Cir. 2013).....53

Gross v. Pfizer, Inc.,
825 F. Supp. 2d 654 (D. Md. 2011), *aff'd sub nom. Drager v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014) 32

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

Hillman v. Maretta,
569 U.S. 483 (2013).....29

Hines v. Davidowitz,
312 U.S. 52 (1941).....29

Hoxworth v. Blinder, Robinson & Co., Inc.,
903 F.2d 186 (3d Cir. 1990) 47

King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.,
791 F.3d 388 (3d Cir. 2015) 6, 33

Leegin Creative Leather Prods., Inc. v. PSKS, Inc.,
551 U.S. 877 (2007).....12

Legend Night Club v. Miller,
637 F.3d 291 (4th Cir. 2011) 52

Lindsey v. Normet,
405 U.S. 56 (1972).....46

Mayo Collaborative Servs. v. Prometheus Labs., Inc.,
566 U.S. 66 (2012).....32

Medtronic, Inc. v. Lohr,
518 U.S. 470 (1996).....35

Morales v. Trans World Airlines, Inc.,
504 U.S. 374 (1992).....46

Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.,
838 F.3d 421 (3d Cir. 2016) 36

N.Y. Life Ins. Co. v. Head,
234 U.S. 149 (1914).....18

Nat'l Collegiate Athletic Ass'n v. Miller,
10 F.3d 633 (9th Cir. 1993) 4, 21, 22

Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.,
472 U.S. 284 (1985).....37, 38

Ohio Oil Co. v. Conway,
279 U.S. 813 (1929) (per curiam).....48

Ohio v. Am. Express Co.,
138 S. Ct. 2274 (2018).....11, 37

Pfaff v. Wells Elecs., Inc.,
525 U.S. 55 (1998).....32

Philip Morris USA v. Williams,
549 U.S. 346 (2007).....46

Pike v. Bruce Church, Inc.,
397 U.S. 137 (1970).....18, 24

PLIVA, Inc. v. Mensing,
564 U.S. 604 (2011).....30

Rocky Mountain Farmers Union v. Corey,
730 F.3d 1070 (9th Cir. 2013) 4, 24, 26

S.D. Myers, Inc. v. City & Cty. of S.F.,
253 F.3d 461 (9th Cir. 2001) 21

Sabri Props, LLC v. City of Minneapolis,
No. 18-cv-3098 (MJD/HB), 2019 WL 2052597
(D. Minn. May 9, 2019).....39

Sam Francis Found. v. Christies, Inc.,
784 F.3d 1320 (9th Cir. 2015) (en banc) 4, 20, 22, 24

Sandoz Inc. v. Amgen Inc.,
137 S. Ct. 1664 (2017).....2

Shell Offshore, Inc. v. Greenpeace, Inc.,
709 F.3d 1281 (9th Cir. 2013) 17

Short v. Brown,
893 F.3d 671 (9th Cir. 2018) 17

Speiser v. Randall,
357 U.S. 513 (1958).....44

United States ex rel. Taxpayers Against Fraud v. Singer Co.,
889 F.2d 1327 (4th Cir. 1989) 48

Teva Pharm. USA, Inc. v. Sebelius,
595 F.3d 1303 (D.C. Cir. 2010).....3, 30

Timbs v. Indiana,
139 S. Ct. 682 (2019).....6, 39

United States v. $100,348.00 in U.S. Currency,
354 F.3d 1110 (9th Cir. 2004) 40

United States v. $132,245.00 in U.S. Currency,
764 F.3d 1055 (9th Cir. 2014) 40, 41

United States v. Altareb,
758 F. App'x 116 (2d Cir. 2018) 40

United States v. Bajakajian,
524 U.S. 321 (1998).....6, 38, 40

United States v. Mackby,
261 F.3d 821 (9th Cir. 2001) 7, 39, 40

United States v. Morrow,
368 F. Supp. 2d 863 (C.D. Ill. 2005) 44

United States v. U.S. Gypsum Co.,
333 U.S. 364 (1948).....33

WCI, Inc. v. Ohio Dep't of Pub. Safety,
774 F. App'x 959 (6th Cir. 2019) 38

Williams v. First Nat'l Bank of Pauls Valley,
216 U.S. 582 (1910).....41

Winter v. Nat. Res. Def. Council, Inc.,
555 U.S. 7 (2008).....7

World-Wide Volkswagen Corp. v. Woodson,
444 U.S. 286 (1980).....18

Statutes

21 U.S.C. § 355(j).....8, 30

28 U.S.C. § 1331.....17

35 U.S.C. § 261.....35, 36

42 U.S.C. § 262(*l*).....3

42 U.S.C. § 1983.....17

Cal. Bus. & Profs. Code § 4073(a).....46

Cal. Civ. Code § 986(a).....20

Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585.....5, 8, 29, 33

Patent Act, 35 U.S.C. § 101 *et seq.*.....9, 27, 32, 36

Other Authorities

Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2016 2 (May 2019), https://bit.ly/2moUyf2.....34

Ass'n for Accessible Meds., *The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report* 4 (2019), https://bit.ly/2ojfghJ.....1, 52

Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 391 (2010).....49

Bret M. Dickey & Daniel L. Rubinfeld, *Would the Per Se Illegal Treatment of Reverse Payment Settlements Inhibit Generic Drug Investment?*, 8 J. COMPETITION L. & ECON. 615, 622 (2012).....51

Bryan A. Liang, *Regulating Follow-on Biologics*,
44 HARV. J. ON LEGIS. 363, 369 (2007) 2

11A Charles Alan Wright et al.,
Federal Practice & Procedure § 2948.1 (3d ed.).....50

H.R. Rep. No. 98-857, pt. 1 (1984),
reprinted in 1984 U.S.C.C.A.N. 2647.....5, 29

Hearing on AB 824 Before the Cal. Assemb. Comm. on Health at 7,
2019-20 Reg. Sess. (Mar. 26, 2019), https://bit.ly/31IfPiS 28

IMS Inst. for Healthcare Informatics, *Impact of Patent Settlements on Drug Costs: Estimation of Savings* 4 (June 2013),
https://bit.ly/2pC5uaA.....10

Lex Machina Releases Fourth Hatch-Waxman/ANDA Litigation Report (May 3, 2018), https://bit.ly/2JnHSxo 41

Malathi Nayak, *Costs Soar for Trade Secrets, Pharma Patent Suits, Survey Finds*, BLOOMBERG LAW (Sept. 10, 2019),
https://bit.ly/2ki106U 9

Marshall Leaffer, *Patent Misuse and Innovation*,
10 J. HIGH TECH. L. 142 (2010) 10

RBC Capital Mkts., *Pharmaceuticals: Analyzing Litigation Success Rates* 4 (Jan. 15, 2010), https://bit.ly/2LPXaga.....9

Report on Branded Drug Firms' Patent Settlements with Generic Competitors (May 23, 2019), http://bit.ly/2I1Rwof 12

Richard A. Samp, *The Role of State Antitrust Law in the Aftermath of* Actavis, 15 MINN. J.L. SCI. & TECH. 149, 150 (2014).....27

Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*,
49 ANTITRUST BULL. 655, 676 (2004) 49

Robin Feldman, *May Your Drug Price Be Evergreen*,
5 J. L. & BIOSCI. 590, 597 (2018) 31

Saul P. Morgenstern & Adam M. Pergament, *Commentary: Applying the Rule of Reason in the Post*-Actavis *World*, 2018 COLUM. BUS. L. REV. 45, 69 (2018) 33

Sen. Susan Collins, *Working to Keep Lifesaving Medications Affordable* (Sep. 2, 2016), https://bit.ly/2ORwaLQ 51

U.S. Const. amend. VIII.....6, 38

U.S. Const. Art. I, § 8, cl. 3.....3

U.S. Const. Art. VI, cl. 2.....28

INTRODUCTION

The cost of healthcare is a problem. Generic medicines are part of the solution. In 2018, generics accounted for 90% of the prescriptions dispensed in the United States (up from 75% in 2009), but just 22% of total drug spending. Ass'n for Accessible Meds., *The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report* 4 (2019), https://bit.ly/2ojfghJ ("2019 Report"). The resulting savings are staggering. The presence of generic alternatives to high-priced brand-name drugs saved Americans nearly ***$2 trillion*** over the last decade, including almost $300 billion last year alone. *Id.* It is no hyperbole to say that generic competition has been one of the most successful methods for lowering healthcare costs in twenty-first-century America.

Nor is it hyperbole to say that much of these savings would not have been possible without patent settlements. A generic medicine generally cannot enter the market while the patent protecting a brand-name drug remains in effect. For that reason, patent litigation between brand-name drug companies and generic competitors is a central mechanism for the timely market entry of low-priced generic alternatives. But patent litigation is exorbitantly expensive, and often brand-name drugs are protected by many (rather than just one) patents. If generic manufacturers need to litigate every patent blocking their entry all the way to judgment, then few generic medicines will be able to enter the market in a timely manner—not only

because there will be fewer settlements, but also because generic companies will bring fewer patent challenges in the first place. Absent the option to settle patent disputes, then, the federal pharmaceutical system will be back at square one, with fewer generics on the market and higher prices for patients.

California's recently enacted Assembly Bill 824 ("AB 824" or "the Act") nonetheless takes that option off the table in many (if not most) cases. AB 824 (attached as Exhibit A to the Complaint) renders run-of-the-mill patent settlements prohibitively risky for generic and biosimilar manufacturers, and thus makes it all but certain that prices for patients.[1] It establishes a near-blanket presumption that pharmaceutical patent settlements are anticompetitive and unlawful. The statute also imposes massive monetary penalties, and extends those penalties to individuals who purportedly "assist[]" in the settlement process. Compl. Ex. A § 134002(e)(1)(A)(i). Each party that violates AB 824 "shall forfeit and pay … a civil penalty … [of] up to ***three times the value***" of the settlement. *Id.* (emphasis added). And "[e]ach ***person***" that even so much as "assists in [a party's] violation" is liable for a "civil penalty" of ***at least $20 million***, even if the person did "not receive[] ***any value***" as

[1] Biosimilars are to biologics—large-molecule medicines derived from living "biological sources such as animals or microorganisms"—as generics are to traditional brand-name medicines, which unlike biologics "are typically synthesized from chemicals." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669-70 (2017); *see* Bryan A. Liang, *Regulating Follow-on Biologics*, 44 HARV. J. ON LEGIS. 363, 369 (2007).

a result of the supposedly offending settlement. *Id.* § 134002(e)(1)(A)(ii) (emphases added).

AB 824 is thus bad policy. The new statute will make generic manufacturers far less likely to "stick out their necks" and file the patent challenges that usually provoke patent litigation. *Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1318 (D.C. Cir. 2010); *see Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 407 (2012) ("Filing a paragraph IV certification means provoking litigation"). It will have the same effect on biosimilar manufacturers, as the Biologics Price Competition and Innovation Act of 2009 contains a similar litigation mechanism. *See* 42 U.S.C. § 262(*l*). And it therefore will diminish the availability of low-priced generic and biosimilar medicines, causing prescription drug prices to skyrocket and the public health to suffer.

More importantly for this Court, AB 824 is unconstitutional. First, AB 824 directly regulates commercial transactions that take place in other states, in violation of the Commerce Clause, U.S. Const. Art. I, § 8, cl. 3. AB 824 contains no language limiting it to agreements that were negotiated, completed, or entered in California; nor is it limited to agreements between or among California entities. The statute applies to all patent settlements between brand-name drug companies and generic/biosimilar developers anywhere in the country, even if the settlement and the settling parties have no connection to the state. AB 824 thus does not merely

"affect[] transactions that take place across state lines"; it directly ***regulates*** transactions that take place "entirely outside of the state's borders." *Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608, 614 (9th Cir. 2018) (citation omitted). Indeed, the statute imposes sweeping "civil … penalties on non-compliant transactions completed wholly out of state." *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1103 (9th Cir. 2013). AB 824 therefore "constitutes a per se violation of the Commerce Clause" under a straightforward application of binding caselaw. *Nat'l Collegiate Athletic Ass'n v. Miller*, 10 F.3d 633, 640 (9th Cir. 1993); *see also Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1323-24 (9th Cir. 2015) (en banc) ("'[W]hether or not the commerce has effects within the State," California may not "regulate[] a commercial transaction that 'takes place wholly outside of the State's borders.'" (quoting *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989))).

Second, AB 824 frustrates the basic purposes of the federal patent laws and is therefore preempted. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000) (a state law that "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" is preempted (citation omitted)). In light of the draconian presumption it erects and the sweeping penalties it imposes, AB 824's immediate effect will be to scuttle patent settlements now in the works, and its eventual effect will be to dissuade generics and biosimilars from challenging

patents—and trying to enter the market prior to patent expiry—at all. The inevitable consequence of the new state statute will thus be fewer Abbreviated New Drug Application ("ANDA") filings with Paragraph IV certifications, fewer challenges to the patents protecting high-priced brand-name drugs, fewer low-priced generic alternatives on the market, and, ultimately, higher prescription drug prices. That is exactly the opposite of what Congress intended the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585, to achieve. *See* H.R. Rep. No. 98-857, pt. 1, at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647 (Congress intended the Hatch-Waxman Act to "make available more low cost generic drugs").

AB 824 also upsets the delicate balance that Congress struck in the patent laws and that the Supreme Court went out of its way to protect in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). *See Farina v. Nokia Inc.*, 625 F.3d 97, 123 (3d Cir. 2010) ("The Supreme Court's preemption case law indicates that regulatory situations in which [the government] is required to strike a balance between competing statutory objectives lend themselves to a finding of conflict preemption."). Patent law "strikes a delicate balance between creating 'incentives that lead to creation, invention, and discovery' and 'imped[ing] the flow of information that might permit, indeed spur, invention,'" *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 590 (2013) (alteration in original) (citation omitted), and the Hatch-Waxman Act likewise "balance[s] the goal of 'mak[ing] available more low cost generic drugs,'

with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement," *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp*., 791 F.3d 388, 394 (3d Cir. 2015) (second set of brackets in original) (citations omitted). *Actavis* held that antitrust review of patent settlements is consistent with these interlocking balances only for settlements with a "large and unjustified" payment from the patent holder to the patent challenger—and even then, only pursuant to the rule of reason. 570 U.S. at 158-59. AB 824 fundamentally upsets that balance. Not only does it subject to antitrust review most pharmaceutical patent settlements with ***any*** transfer of "value" from brand to generic, it does away with the rule of reason entirely, placing the burden on the defendant to prove that the agreement is ***not*** anticompetitive.

Furthermore, the penalties AB 824 imposes are grossly disproportionate to the conduct supposedly justifying them in violation of the Eighth Amendment's Excessive Fines Clause, U.S. Const. amend. VIII. Under AB 824, every executive, lawyer, negotiator, or other "person" who played any role in hammering out a supposedly offending settlement is liable for a "civil penalty" of ***at least $20 million***, even if she did "not receive[] ***anything of value***" as a result. Compl. Ex. A § 134002(e)(1)(A)(ii) (emphasis added). It is difficult to imagine a more obvious violation of the Excessive Fines Clause. *See Timbs v. Indiana*, 139 S. Ct. 682, 687 (2019) (holding that Excessive Fines Clause applies to the states); *United States v.*

Bajakajian, 524 U.S. 321, 328-34 (1998) (civil penalties are "fines" for purposes of the Clause); *see also United States v. Mackby*, 261 F.3d 821, 829 (9th Cir. 2001) (a civil fine "is unconstitutionally excessive if" it "is grossly disproportionate to the gravity of the defendant's offense").

The Association for Accessible Medicines ("AAM") is thus very likely to succeed on the merits of its claims. The remaining preliminary injunction factors likewise favor granting AAM's motion. AAM's members are "likely to suffer irreparable harm in the absence of preliminary relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). AB 824 exponentially raises the risk and potential cost of settling patent disputes, and thus essentially removes the main mechanism by which AAM's members are able to make their generic and biosimilar medicines available to patients in a timely manner. *See, e.g.*, Declaration of Brij Khera ¶¶ 8-9 (Ex. 1); Declaration of Craig Kuchii ¶¶ 6-7 (Ex. 2); Declaration of Robert Matsuk ¶¶ 6-10 (Ex. 3); Declaration of Colman B. Ragan, Esq. ¶¶ 9-10 (Ex. 4); Declaration of Jack C. Silhavy ¶¶ 5-6 (Ex. 5); Declaration of Anne Wilson (Mylan Witness) ¶¶ 10-11 (Ex. 6). That will cause textbook irreparable injuries. It will also cost AAM's members millions of dollars, precisely none of which they will ever be able to recoup given the Attorney General's Eleventh Amendment protection. Moreover, subjecting AAM's members to an unconstitutional law will cause irreparable harm all on its own. The balance of equities and the public interest

support AAM's request as well. A state suffers no cognizable harm by being enjoined from enforcing an unconstitutional law, and enforcement of an unconstitutional law is always contrary to the public interest. But even putting the merits to the side, the public-interest case for enjoining AB 824 could hardly be stronger. AB 824 will lead to fewer generic medicines on the market. By contrast, enjoining AB 824 will help ensure that patients have timely access to the low-priced medicines they need. For these reasons, and as further set forth below, the Court should grant AAM's motion.

STATEMENT OF FACTS

A. Patent Settlements Save Americans Billions of Dollars in Healthcare Costs Every Year.

Patent litigation is the main market-entry mechanism for generic medicines. Under the Hatch-Waxman Act, the FDA may approve generic versions of already-approved brand-name drugs on the basis of less-costly ANDAs, which "show[] that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Caraco*, 566 U.S. at 405. But generics cannot enter the market whenever they please because "the FDA cannot authorize a generic drug that would infringe a patent." *Id.* "[A] company filing an ANDA," therefore, "must assure the FDA that its proposed generic drug will not infringe the brand's patents." *Id.* at 405-06. One common option for providing that assurance "is to file a so-called paragraph IV certification, which states that a listed patent 'is invalid or will not be

infringed by the manufacture, use, or sale of the [generic] drug.'" *Id.* at 407 (alteration in original) (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). "Filing a paragraph IV certification," however, "means provoking litigation," as the Patent Act, 35 U.S.C. § 101 *et seq.*, "treats such a filing as itself an act of infringement." *Caraco*, 566 U.S. at 407. Litigation is thus inherent in the process by which low-priced generic medicines enter the market pursuant to federal law.

So is settlement. Patent litigation is exorbitantly expensive. "[T]he cost of litigation in this specific context—a generic challenging a brand name pharmaceutical patent—was about $10 million per suit" a decade ago, *Actavis*, 570 U.S. at 170 (Roberts, C.J., dissenting) (citing study), and the costs have only increased since then, *see* Malathi Nayak, *Costs Soar for Trade Secrets, Pharma Patent Suits, Survey Finds*, BLOOMBERG LAW (Sept. 10, 2019) (median cost rose 67% between 2015 and 2019), https://bit.ly/2ki106U. And there is no guarantee that challenging a patent will be successful and thus pave the way for the generic's market entry. In fact, when Paragraph IV suits are litigated to judgment, the generic prevails over the patentee less than half the time. *See* RBC Capital Mkts., *Pharmaceuticals: Analyzing Litigation Success Rates* 4 (Jan. 15, 2010) (generic success rate under 50%), https://bit.ly/2LPXaga; Br. for the Generic Pharm. Ass'n as *Amicus Curiae* Supporting Resp'ts, *FTC v. Actavis, Inc.* (No. 12-416), 2013 WL 769341, at *16-17 (U.S. Feb. 28, 2013) (similar for secondary patents).

Even in single-patent cases, the risks of litigating to judgment will often outweigh the expected value for the generic. After all, generic and biosimilar manufacturers typically operate on thin margins; a single patent is enough to keep all generic competitors off the market; and a single patent lawsuit typically costs millions of dollars. Unfortunately, it is increasingly rare for a major brand-name drug to be protected by only a single patent. Brand-name drug companies now often file "follow-on" patent applications, which, if granted, extend the exclusivity period protecting their products multiple additional years—and accordingly raise the cost of patent litigation many times over. *See generally* Marshall Leaffer, *Patent Misuse and Innovation*, 10 J. HIGH TECH. L. 142 (2010).

In sum, patent settlements are necessary for generics to enter the market in a timely manner. Indeed, without the option to settle, generics likely would not bring as many patent challenges in the first place—and much of the savings generics have unlocked would not have been possible if the option of settling patent disputes had not been on the table. *See* IMS Inst. for Healthcare Informatics, *Impact of Patent Settlements on Drug Costs: Estimation of Savings* 4 (June 2013) (patent settlements moved up generic entry by an average of 81 months, or 6.75 years), https://bit.ly/2pC5uaA.

B. The Supreme Court Confirms that Most Patent Settlements Are Procompetitive and Lawful.

In *Actavis*, the FTC "urge[d the Supreme Court] to hold that reverse payment settlement agreements"—*i.e.*, settlements in which the brand manufacturer agrees to provide compensation to the ANDA filer—"are presumptively unlawful and that courts reviewing such agreements should proceed via a 'quick look' approach, rather than applying a 'rule of reason.'" 570 U.S. at 158-59. The Supreme Court "decline[d] to do so," and for a simple reason: Settlements that allow generic entry before the expiration of the brand-name drug's monopoly "bring about competition … to the consumer's benefit." *Id.* at 154, 159.

At the same time, however, the Court recognized that patent settlements have "the 'potential for genuine adverse effects on competition'" when the payment is not a "rough approximation of the litigation expenses saved" or "compensation for other services." *Id.* at 153, 156. Such an "unexplained" so-called reverse payment, the Court reasoned, might "suggest that the patentee has serious doubts about the patent's survival," and thus might mean that the brand had purchased the delay in generic entry using undue monopoly profits. *Id.* at 154-57. In that case, the settlement might indeed be anticompetitive. *See id.* at 158. But because most patent settlements, including those that "allow[] the generic manufacturer to enter the patentee's market prior to the patent's expiration," are ***not*** anticompetitive, the Court imposed a bright line: Only settlements with "***unjustified***" and "***large***" payments

from the brand to the generic may be subjected to antitrust scrutiny—and even then, only under the rule of reason. *Id.* at 157-59; *see Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018) ("The rule of reason requires courts to conduct a fact-specific assessment of 'market power and market structure … to assess the [restraint]'s actual effect' on competition." (ellipsis and alteration in original) (quoting *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768 (1984))); *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 885 (2007) (Under the rule of reason, the factfinder "weighs all of the circumstances of a case in deciding whether" an agreement "should be prohibited as imposing an unreasonable restraint on competition." (citation omitted)).

Since the Court decided *Actavis*, the total number of patent settlements has increased, but the number of anticompetitive settlements has decreased substantially. *See* Press Release, FTC, *FTC Staff Issues FY 2016 Report on Branded Drug Firms' Patent Settlements with Generic Competitors* (May 23, 2019), http://bit.ly/2I1Rwof. Indeed, according to the FTC Chairman, "the Supreme Court's Actavis decision has significantly reduced the kinds of reverse payment agreements that are most likely to impede generic entry and harm consumers." *Id.*; *see also id.* ("Only a single agreement" in FY 2016 "contained a side deal or no-AG commitment," which was "the lowest number of such agreements since 2004.").

C. California Enacts AB 824.

Against this backdrop, California enacted AB 824 earlier this year. The new statute, which Governor Newsom signed on October 7, 2019, not only jettisons *Actavis*' constraints in antitrust suits brought by the California Attorney General, it turns the delicate balance underlying *Actavis* upside down. Adding injury to insult, the statute prohibits patent settlements ***anywhere in the country*** so long as the settlement confers "anything of value" from the brand to the generic and includes delayed generic or biosimilar entry—with the "delay" being measured against the hypothetical world in which the brand-name manufacturer agrees to allow the immediate entry of a lower-priced competitor notwithstanding its patent protection.

Under AB 824, "an agreement resolving or settling, on a final or interim basis, a patent infringement claim in connection with the sale of a pharmaceutical product ***shall be presumed to have anticompetitive effects and shall be a violation of this section***" whenever two conditions are met: (1) the generic or biosimilar manufacturer "receives ***anything of value*** from [the brand] company" as part of the settlement; and (2) the generic or biosimilar manufacturer "agrees to limit or forego research, development, manufacturing, marketing, or sales of [its generic or biosimilar] product ***for any period of time***." Compl. Ex. A § 134002(a)(1) (emphases added). In other words, unless the agreement gives the generic or

biosimilar manufacturer nothing ***and*** allows it to immediately sell its allegedly infringing product, the agreement is almost certainly presumptively unlawful.

The Act defines the term "anything of value" expansively. Under § 134002(a)(1)(A), the term "includ[es], but [is] not limited to, an exclusive license or a promise that the brand company will not launch an authorized generic version of its brand drug." However, "consideration granted by the brand … to the [generic]" that "consists of only one or more of the following" may not form the basis of liability:

> (A) The right to market the competing product in the United States before the expiration of [the brand's relevant patent].
>
> (B) A covenant not to sue on a claim that the [generic or biosimilar] drug product infringes a United States patent.
>
> (C) Compensation for saved reasonable future litigation expenses of the [generic or biosimilar manufacturer] but only if both of the following are true:
>
> > (i) The total compensation for saved litigation expenses is reflected in budgets that the [brand manufacturer] documented and adopted at least six months before the settlement.
> >
> > (ii) The compensation does not exceed the lower of … $7,500,000 [or] [f]ive percent of the revenue that the [generic or biosimilar manufacturer] projected or forecasted it would receive in the first three years of sales of its version of the [patented] drug documented at least 12 months before the settlement ….
>
> (D) An agreement resolving or settling a patent infringement claim that permits a [generic or biosimilar manufacturer] to begin selling, offering for sale, or distributing the [generic or biosimilar] drug product if the [brand manufacturer] seeks approval to launch, obtains approval to

> launch, or launches a different dosage, strength, or form of the [patented] drug having the same active ingredient before the date set by the agreement for entry of the [generic or biosimilar manufacturer]. A different form of the [patented] drug does not include an authorized generic version of the [patented] drug.
>
> (E) An agreement by the [brand manufacturer] not to interfere with the [generic or biosimilar manufacturer] ability to secure and maintain regulatory approval to market the [generic or biosimilar] drug product or an agreement to facilitate the [generic or biosimilar manufacturer's] ability to secure and maintain regulatory approval to market the [generic or biosimilar] drug product.
>
> (F) An agreement resolving a patent infringement claim in which the [brand manufacturer] forgives the potential damages accrued by a [generic or biosimilar manufacturer] for an at-risk launch of the [generic or biosimilar] drug product that is the subject of that claim."

Id. § 134002(a)(2).

To rebut the presumption of illegality, a party must prove by a preponderance of the evidence that "[t]he value received by the [generic or biosimilar manufacturer]" as part of the agreement "is a fair and reasonable compensation ***solely for other goods or services*** that the [generic or biosimilar manufacturer] has promised to provide," or that "[t]he agreement has directly generated procompetitive benefits ***and*** the procompetitive benefits … outweigh [its] anticompetitive effects." *Id.* § 134002(a)(3) (emphases added). The statute does not define "fair and reasonable." Nor does the statute explain how a defendant can prove that a settlement agreement already "has" generated procompetitive benefits when the agreement authorizes the generic or biosimilar to enter the market in the future, but

still years before patent expiry. In determining whether the defendant has rebutted the presumption of anticompetitive effect, AB 824 forbids the finder of fact from assuming, *inter alia*, that generic entry "could not have occurred until the expiration of the relevant patent exclusivity or that the agreement's provision for entry of the [generic or biosimilar] drug product before the expiration of any patent exclusivity means that the agreement is procompetitive," that the relevant patent "is enforceable and infringed," or that "the agreement caused no delay in entry of" the generic manufacturer's product because of the lack of FDA approval. *Id.* § 134002(b).

AB 824 also imposes severe penalties. "Each person that violates or assists in the violation of this section" and who "received any value due to that violation" "shall forfeit and pay to the State of California a civil penalty" of "up to three times the value received by the party that is reasonably attributable to the violation of this section, or twenty million dollars ($20,000,000), whichever is greater." *Id.* § 134002(e)(1)(A)(i). Even a "person that violates or assists in the violation of this section" but who "has ***not*** received anything of value" therefrom "shall forfeit and pay to the State of California a civil penalty" of "up to three times the value given to other parties to the agreement reasonably attributable to the violation of this section, or twenty million dollars ($20,000,000), whichever is greater." *Id.* § 134002(e)(1)(A)(ii) (emphasis added); *see id.* § 134002(e)(1)(A)(iii) (what is "'reasonably attributable to the violation' shall be determined by California's share

of the market for the brand drug at issue in the agreement"). Those penalties "shall accrue only to the State of California and shall be recovered in a civil action brought by the Attorney General in its own name, or by any of its attorneys designated by it for that purpose, against any party to an agreement that violates this section." *Id.* § 134002(e)(1)(B).

AB 824 contains no language limiting its application to settlement agreements between California entities. Nor does it contain language limiting its application to agreements negotiated, signed, and/or entered in California courts.

JURISDICTION

AAM challenges the validity of provisions of the Act under 42 U.S.C. § 1983 as well as the U.S. Constitution. This Court has jurisdiction under 28 U.S.C. § 1331.

ARGUMENT

"Plaintiffs seeking a preliminary injunction must establish that: (1) they are likely to succeed on the merits; (2) they are likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in their favor; and (4) an injunction is in the public interest." *Short v. Brown*, 893 F.3d 671, 675 (9th Cir. 2018). Even "where there are only 'serious questions going to the merits'—that is, less than a 'likelihood of success' on the merits—a preliminary injunction may still issue so long as 'the balance of hardships tips *sharply* in the plaintiff's favor' and the

other two factors are satisfied." *Id.* (quoting *Shell Offshore, Inc. v. Greenpeace, Inc.*, 709 F.3d 1281, 1291 (9th Cir. 2013)). Each factor favors injunctive relief here.

I. AAM Is Likely To Succeed On The Merits.

A. AB 824 Directly Regulates Transactions that Take Place in Other States and Therefore Violates the Commerce Clause.

The Commerce Clause prohibits states from "regulating commerce occurring wholly outside [their] borders." *Healy v. Beer Inst.*, 491 U.S. 324, 332 (1989). This prohibition is an essential element of our constitutional system. *See N.Y. Life Ins. Co. v. Head*, 234 U.S. 149, 161 (1914) (territorial constraint is an "obvious[]" and "necessary result of the Constitution"); *see also World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 293 (1980) ("The sovereignty of each State … implie[s] a limitation on the sovereignty of all of its sister States" that is inherent in "the original scheme of the Constitution …."). As such, the prohibition on regulating transactions that take place out of state applies ***even if*** the "extraterritorial reach was [not] intended by the legislature," and ***even if*** the transaction at issue "has effects within the State." *Healy*, 491 U.S. at 335-36 (citations omitted). Indeed, the prohibition applies not only where a state law explicitly regulates extraterritorial conduct, but also where "***the practical effect*** of the regulation is to control conduct beyond the boundaries of the State." *Id.* at 336 (emphasis added).

To be sure, each state possesses broad authority to regulate conduct in its respective sphere. A law that "has only indirect effects on interstate commerce," but

does not actually ***regulate*** out-of-state transactions, will therefore be upheld unless "the burden" it imposes on interstate commerce "clearly exceeds the local benefits." *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986); *see Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). But each state's authority "is not only subordinate to the federal power over interstate commerce, but is also constrained by the need to respect the interests of other States." *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 571-72 (1996) (citations omitted). State laws that impose penalties on transactions that take place entirely in other states are therefore "virtually *per se* invalid under the Commerce Clause." *Brown-Forman*, 476 U.S. at 579; *see Dean Foods Co. v. Brancel*, 187 F.3d 609, 615 (7th Cir. 1999) ("There is a long line of cases holding that states violate the Commerce Clause by regulating or controlling commerce occurring wholly outside their own borders.").

The Supreme Court's decision in *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935), is instructive. At issue in *Baldwin* was a wholesale transaction between a Vermont "creamery" (manufacturer) and a New York "milk dealer" (distributor), which occurred in Vermont. *Id.* at 518. All agreed that the milk sold in that out-of-state transaction was intended for sale in New York. Indeed, the New York Milk Control Act, the statute at issue in the case, "applied only to milk that would eventually be sold to New York consumers." *Carolina Trucks & Equip., Inc. v. Volvo Trucks of N. Am., Inc.*, 492 F.3d 484, 491 (4th Cir. 2007) (discussing *Baldwin*). Yet

that limitation—*i.e.*, the fact that the statute only reached transactions that were upstream of an in-state consumer transaction—did not save the statute. The New York Milk Control Act mandated that "milk bought outside" New York could not be sold "within the state" unless the price paid in the out-of-state transaction conformed to the price requirements New York imposed "upon a like transaction within the state." *Baldwin*, 294 U.S. at 519. And the practical effect of that prohibition was to impose requirements on transactions that occurred entirely outside New York. The Court thus struck down the statute, holding that although New York had ample power to protect its citizens when it comes to in-state commerce, it "has no power to project its legislation into Vermont" or any other state. *Id.* at 521.

The law of this Circuit is entirely in accord, as the recent decision in *Sam Francis Foundation v. Christies, Inc.*, 784 F.3d 1320 (9th Cir. 2015) (en banc), makes clear. *Sam Francis* involved a challenge to California's Resale Royalty Act, which "requires the seller of fine art to pay the artist a five percent royalty if 'the seller resides in California or the sale takes place in California.'" *Id.* at 1322 (quoting Cal. Civ. Code § 986(a)). The plaintiffs argued that the statute violated the Commerce Clause with respect to "sales outside the State of California." *Id.* The Ninth Circuit "easily conclude[d]" that they were correct. *Id.* at 1323. The court acknowledged that the statute regulated out-of-state sales only when they involved a California resident, and that "in some circumstances, the royalty amount eventually may wind

up, through a form of escheat, in a special fund of the State's coffers." *Id.* at 1323-24. But those "connection[s] with the state" did not save the statute, because the "constitutional rule" operates without exception: "[W]hether or not the commerce has effects within the State," California may not "regulate[] a commercial transaction that 'takes place wholly outside of the State's borders.'" *Id.* at 1323-25 (quoting *Healy*, 491 U.S. at 336); *see also, e.g.*, *Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608, 612-16 (9th Cir. 2018) (enjoining California law that purported to "dictate the method by which" medical-waste companies treated medical waste "outside of California" on the ground that it "reach[ed] beyond the borders of California [to] control transactions that occur wholly outside of the State"); *Nat'l Collegiate Athletic Ass'n v. Miller*, 10 F.3d 633, 639 (9th Cir. 1993) ("*NCAA*") (invalidating Nevada law imposing procedural requirements on NCAA enforcement proceedings on the ground that it had "the practical effect" of "requir[ing]" the NCAA to apply Nevada's preferred procedural rules "in enforcement proceedings in every state in the union"); *cf. Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1358-59 (Fed. Cir. 2013) (vacating California-law injunction with practical effect of "impos[ing]" California statute "on entirely extraterritorial conduct").

AB 824 cannot be remotely reconciled with that well-settled case law. AB 824 contains no restrictions that limit its application to settlement agreements that were negotiated, completed, or entered in California. Nor is AB 824 limited to

agreements between or among California entities. To the contrary, it applies to ***all patent settlements*** between brands and generics/biosimilars ***anywhere in the country***, even if the settling parties have no connection to the state. AB 824 thus does not merely "affect[] transactions that take place across state lines"; it directly ***regulates*** transactions that take place "entirely outside of the state's borders." *Daniels Sharpsmart*, 889 F.3d at 614 (quoting *S.D. Myers, Inc. v. City & Cty. of S.F.*, 253 F.3d 461, 467 (9th Cir. 2001)). As such, it "constitutes a per se violation of the Commerce Clause." *NCAA*, 10 F.3d at 639-40.

Imagine the following: After a generic manufacturer headquartered and incorporated in Pennsylvania files an ANDA with a Paragraph IV certification, the brand manufacturer responds by filing suit in federal court in Pennsylvania, where it too is headquartered and incorporated. *See Caraco*, 566 U.S. at 407 ("Filing a paragraph IV certification means provoking litigation."). The parties ultimately settle. All settlement negotiations take place in Pennsylvania; the deal is signed in Pennsylvania; and the agreement is entered in a Pennsylvania federal court. With respect to California, that agreement would be "out-of-state" commerce in every sense. Yet under AB 824, that agreement could still form the basis of a massive "penalty," *see* Compl. Ex. A § 134002(e)(1)(A), even if the agreement is perfectly lawful under federal law. Indeed, the only way the settling parties could avoid California-law penalties would be to alter the settlement terms to conform to

California's (perverse) new view of competition. AB 824 is thus a textbook direct regulation of "a commercial transaction that 'takes place wholly outside of the State's borders,'" in violation of the Commerce Clause. *Sam Francis*, 784 F.3d at 1323-24 (quoting *Healy*, 491 U.S. at 336); *see also, e.g.*, *Ass'n for Accessible Med. v. Frosh*, 887 F.3d 664, 672 (4th Cir. 2018) (striking down Maryland statute that "effectively seeks to compel manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland"), *cert. denied*, 139 S. Ct. 1168 (2019).

The Attorney General likely will argue that AB 824 is merely a consumer-protection statute designed to protect Californians first and foremost. And to be sure, the statute does not expressly refer to out-of-state agreements or to interstate commerce more generally. But as *Brown-Forman* makes clear, that is of no moment. The fact that a state law "is addressed only to sales … in [the state] ***is irrelevant*** if the 'practical effect' of the law" is to regulate conduct "in other States." *Brown-Forman*, 476 U.S. at 583 (citations omitted). And AB 824 on its face seeks "to punish" pharmaceutical companies for settling patent-infringement disputes "in a manner" that California disapproves of. *Daniels Sharpsmart*, 889 F.3d at 616.

AB 824 is thus different—on the dimension that matters—from the California statutes the Ninth Circuit recently has upheld against Commerce Clause challenges. *See, e.g.*, *Chinatown Neighborhood Ass'n v. Harris*, 794 F.3d 1136, 1139-47 (9th Cir. 2015) (rejecting Commerce Clause challenge to California law that "makes it

'unlawful for any person to possess, sell, offer for sale, trade, or distribute a shark fin' in the state"); *Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937, 949-51 (9th Cir. 2013) (rejecting Commerce Clause challenge to California law that forbids sales "within California" of products produced by force-feeding birds but does not apply to sales "outside the boundaries of California"). The statutes in those cases surely had ***effects*** on interstate commerce, given California's outsized role in the American economy. But the statutes in those cases did not actually ***regulate*** any transactions that took place in other states. *See Sam Francis*, 784 F.3d at 1324 (explaining that such cases "concerned state laws that regulated ***in-state conduct*** with allegedly significant out-of-state practical effects"). And as the Ninth Circuit has made clear, state laws that "impose[] no civil or criminal penalties on non-compliant transactions completed wholly out of state" are subject only to the deferential *Pike* balancing test, not the rule of invalidity. *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1102-03 (9th Cir. 2013).

Unlike those cases, the problem with AB 824 is not merely that it has ***effects*** on transactions that take place in other states (although it surely does). The problem is that AB 824 does precisely what the statute in *Rocky Mountain Farmers Union* did not: "[I]t imposes … penalties on non-compliant transactions completed wholly out of state." *Id.* Under AB 824, a business transaction (*i.e.*, a settlement agreement) between two non-California entities, *see, e.g.*, Khera Decl. ¶ 2 (Zydus) (Ex. 1);

Kuchii Decl. ¶ 2 (SunTaro) (Ex. 2); Matsuk Decl. ¶ 2 (Glenmark) (Ex. 3); Silhavy Decl. ¶ 2 (Fresenius Kabi) (Ex. 5), completed and entered entirely in another state, may be grounds for crippling California-law liability simply because it does not comply with California's policy views. That is exactly what the Commerce Clause prohibits. And unlike traditional state antitrust law, which may authorize remedies or allow the use of procedural devices that are unavailable under federal law, AB 824 imposes an entirely different substantive standard—a standard not only unique to California, but far more draconian than *Actavis* allows—on transactions that take place entirely outside of California. The statute is thus per se invalid under a straightforward application of binding Supreme Court and Ninth Circuit precedent.

AB 824 violates the Commerce Clause in yet another way. "[T]he Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State." *Healy*, 491 U.S. at 336-37. Under AB 824, however, an agreement between two Pennsylvania entities that was negotiated, signed, and entered in Pennsylvania could be deemed procompetitive and lawful under Pennsylvania law (and federal law) but anticompetitive and unlawful under California law. That is precisely the sort of morass the Commerce Clause prohibits states from creating. *See id.* at 336 ("[T]he practical effect of [a state] statute must be evaluated not only by considering the consequences of the statute itself, but also by considering how the challenged statute

may interact with the legitimate regulatory regimes of other States ….”); *see also Daniels Sharpsmart*, 889 F.3d at 616.

Furthermore, “the practical effect of [a state] statute” must also be evaluated “by considering … what effect would arise if not one, but many or every, State adopted similar legislation.” *Healy*, 491 U.S. at 336. And here, the effect is obvious: If every state passed the same draconian anti-settlement legislation, then virtually no patent disputes would ever result in settlement, because companies would be forced to adhere to myriad different—and often inconsistent—statutes. If their ability to settle patent cases were restricted nationwide, such that generic and biosimilar manufacturers could not accept even terms guaranteeing substantially procompetitive outcomes for fear of being forced to ***disprove*** anti-competitiveness and, if unable, of being subjected to sweeping penalties, these generic and biosimilar manufacturers simply would not pursue the same number of patent challenges at the outset. That would mean fewer ANDA and biosimilar filings, fewer patent challenges, and ultimately fewer generics and biosimilars on the market. The “practical effect” of many states adopting similar laws would thus be to gut the intricate system Congress set in place. Such a negative national consequence is precisely what the Commerce Clause protects against.

That is not to say that California lacks the ability to penalize anticompetitive transactions. States certainly “are free to regulate commerce and contracts within

their boundaries with the goal of influencing the out-of-state choices of market participants." *Rocky Mountain Farmers Union*, 730 F.3d at 1103. But states just as certainly "may not mandate compliance with their preferred policies in wholly out-of-state transactions." *Id.* Because that is exactly what AB 824 does vis-à-vis federal patent settlements between non-California entities completed wholly outside of California, AAM is likely to succeed on its Commerce Clause claim.

B. AB 824 Upsets the Delicate Federal Balance Between Competition and Innovation, and Is Therefore Preempted.

Under the Supreme Court's decision in *Actavis*, antitrust review is permissible only with respect to patent settlements that contain a "large and unjustified" payment from the patent holder to the patent challenger—and even then, only pursuant to the rule of reason. 570 U.S. at 158-59. Under AB 824, by contrast, antitrust review is permissible with respect to nearly all patent settlements except those that give the generic/biosimilar manufacturer nothing ***and*** allow the generic/biosimilar manufacturer to sell its allegedly infringing product immediately. And whereas the federal rule of reason requires the challenger to prove that the settlement in fact has anticompetitive effects, AB 824 presumes that critical element.

To be sure, "the federal antitrust laws do not pre-empt state law" in every instance. *California v. ARC Am. Corp.*, 490 U.S. 93, 101-02 (1989). But here, the relevant source of federal law for preemption purposes is federal patent law, not federal antitrust law. And "federal courts have not hesitated to rule that state antitrust

law is preempted by federal law when they determine that state law comes into conflict with some other federal statute," such as the Patent Act and its progeny. Richard A. Samp, *The Role of State Antitrust Law in the Aftermath of* Actavis, 15 MINN. J.L. SCI. & TECH. 149, 150 (2014); *see, e.g.*, *Connell Constr. Co. v. Plumbers & Steamfitters Local Union No. 100*, 421 U.S. 616, 635-36 (1975) (claim arising under state antitrust law preempted by federal labor law even though conduct that gave rise to state claim could proceed under federal antitrust law). Indeed, even the California Supreme Court has recognized not only that "[t]he 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," but also that states "***must abide by [its] judgment" on these issues***. *In re Cipro Cases I & II*, 348 P.3d 845, 859 (Cal. 2015) (emphases added); *see also Farina*, 625 F.3d at 123.

As explained below, AB 824 could not be less consistent with the federal "judgment" here. *See Hearing on AB 824 Before the Cal. Assemb. Comm. on Health* at 7, 2019-20 Reg. Sess. (Mar. 26, 2019) ("This bill establishes a different standard of review for pay-for-delay agreement than what was decided in the FTC v. Actavis case."), https://bit.ly/31IfPiS. It is therefore preempted and invalid. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989) ("[S]tate regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws.").

"The Supremacy Clause provides a clear rule that federal law 'shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (quoting U.S. Const. Art. VI, cl. 2); *see Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378, 1384 (2015) ("the court may issue an injunction upon finding the state regulatory actions preempted"). Under that clear constitutional command, a state law that "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" is preempted and invalid. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

Courts conduct a two-step analysis to determine whether a state law poses an obstacle to federal objectives in violation of the Supremacy Clause. They first ascertain the federal purposes and objectives, and they next determine whether the state law in question "frustrates" those objectives. *Hillman v. Maretta*, 569 U.S. 483, 490-91, 494 (2013) (citation omitted); *see, e.g., Comm'ns Imp. Exp. S.A. v. Republic of the Congo*, 757 F.3d 321, 326 (D.C. Cir. 2014). With respect to AB 824, that analysis leads to a straightforward conclusion: California's new statute is fundamentally inconsistent with the purposes and objectives of the Hatch-Waxman Act.

Hatch-Waxman's basic premise is that the public benefits when a generic pharmaceutical manufacturer opens the market to competition, and its basic purpose

is to get more low-priced generic medicines on the market as soon as possible. *See generally* H.R. Rep. No. 98-857, pt. 1, at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647 (stating objective as "mak[ing] available more low cost generic drugs"). And its basic purpose is "to get generic drugs into the hands of patients at reasonable prices—fast.'" *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (citation omitted). But Congress recognized not only that patent litigation is necessary to get generics onto the market prior to patent expiry, but also that generics are unlikely to take steps to challenge those patents without a "reward" for "stick[ing] out their necks," in light of the high costs of patent litigation. *Teva*, 595 F.3d at 1318. That is why Congress granted a 180-day exclusivity period to the first filer of a substantially complete ANDA with a Paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV), (j)(5)(B)(iv); *see also PLIVA, Inc. v. Mensing*, 564 U.S. 604, 626 (2011) ("Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public."). The balance Hatch-Waxman strikes, in other words, is to restrict inter-generic competition for 180 days on the front end in order to "induce challenges to patents claimed to support brand drugs" and thereby obtain a "pro-consumer" result in the long run. *Teva*, 595 F.3d at 1318.

AB 824 turns that balance on its head. The 180-day exclusivity period certainly helps offset the deterrent effect of the high cost of patent litigation. But not

even that mechanism could make "stick[ing] out their necks" worth generics' while if they had to litigate every patent blocking their less-expensive products' all the way to judgment. As noted, patent litigation is exorbitantly expensive; Paragraph IV litigation is even more so; and the patentee wins such lawsuits more often than not. Furthermore, brand manufacturers are increasingly filing follow-on applications that exponentially raise the number of patents protecting their expensive products. Indeed, between 2005 and 2015, more than three-quarters of all pharmaceutical patent filings were association not with "new drugs coming on the market, but existing drugs," and "[t]he number of drugs that had a patent added on to them almost doubled." Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J. L. & BIOSCI. 590, 597 (2018). Absent the option to settle patent disputes, then, the federal pharmaceutical system would be back at square one—with fewer generics on the market and higher prices for patients. After all, no rational company would spend millions of dollars to develop a new drug if they knew that it would cost them tens of millions more just to have a puncher's chance (or maybe even less than a puncher's chance) of launching their product prior to patent expiry.

In light of the draconian presumption it erects and the sweeping penalties it imposes, AB 824 will do more than simply cause pharmaceutical companies to think twice before settling patent disputes; it will render pharmaceutical patent disputes prohibitively risky—especially for generics and biosimilars, which (unlike their

brand-name counterparts) typically operate on thin margins—and will thus decrease the number of low-price generic medicines entering the market in a timely manner. *See, e.g.*, Khera Decl. ¶¶ 8-9 (Ex. 1); Kuchii Decl. ¶¶ 6-7 (Ex. 2); Matsuk Decl. ¶¶ 8-9 (Ex. 3); Ragan Decl. ¶¶ 9-10 (Ex. 4); Silhavy Decl. ¶¶ 5-6 (Ex. 5); Wilson Decl. ¶¶ 10-11 (Ex. 6). That is exactly the opposite of what Hatch-Waxman was designed to accomplish.

Of course, increasing the price of drugs is not California's aim. But that is exactly what AB 824 will do if allowed to go into effect. And California cannot undo Congress' careful policy to address the national issue of high drug prices by encouraging the availability of more affordable generic alternatives. *See, e.g., Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011) (state laws "compel[ling] generic manufacturers to stop production" of a federally regulated drug "would directly conflict with the federal statutory scheme," and therefore are preempted), *aff'd sub nom. Drager v. PLIVA USA, Inc.*, 741 F.3d 470 (4th Cir. 2014).

AB 824 also upsets the delicate balance that Congress (and the Constitution) struck in the patent laws more generally, *see Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1371-74 (Fed. Cir. 2007), and that the Supreme Court in *Actavis* went out of its way to protect. Patent law "strikes a delicate balance between creating 'incentives that lead to creation, invention, and discovery' and 'imped[ing] the flow of information that might permit, indeed spur, invention.'" *Ass'n for*

Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 590 (2013) (alteration in original) (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 92 (2012)); *see also Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998) (The Patent Act strikes a "balance between the interest in motivating innovation and enlightenment by rewarding invention with patent protection on the one hand, and the interest in avoiding monopolies that unnecessarily stifle competition on the other."). And, as noted, the Hatch-Waxman Act "balance[s] the goal of 'mak[ing] available more low cost generic drugs,' with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement." *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015) (second set of brackets in original) (citations omitted).

Under *Actavis*, antitrust review of patent settlements is consistent with these interlocking federal "balances" only when the settlement contains a "large and unjustified" payment from the patent holder to the patent challenger—and even then, only pursuant to the rule of reason. 570 U.S. at 158-59 (refusing to "abandon[] … the 'rule of reason' in favor of presumptive rules (or a 'quick-look' approach)"); *see* Saul P. Morgenstern & Adam M. Pergament, *Commentary: Applying the Rule of Reason in the Post-*Actavis *World*, 2018 COLUM. BUS. L. REV. 45, 69 (2018) ("The *Actavis* holdings … are clear—no per se rules, no quick looks, no presumptions."); *see also Actavis*, 570 U.S. at 148 (Because "patent and antitrust policies are both

relevant" to the issue, "courts must 'balance the privileges of [the patent holder] and its licensees under the patent grants with the prohibitions of the Sherman Act against combinations and attempts to monopolize.'" (alteration in original) (quoting *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 390-91 (1948))).

AB 824 runs roughshod over that carefully-calibrated regime. For a patent settlement to "be a violation of" AB 824, the generic/biosimilar manufacturer need only "receive[] a[ ]thing of value" and agree not to launch its product immediately. Compl. Ex. A § 134002(a)(1). Yet as recent FTC data confirm, most patent settlements satisfy those conditions. Generic manufacturers "agree[d] to limit or forego research, development, manufacturing, marketing, or sales," *id.* § 134002(a)(1)(B), in almost every patent settlement most recently reviewed by the FTC. *See* Bureau of Competition, FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2016* 2 (May 2019) ("FY 2016 Overview"), https://bit.ly/2moUyf2. That makes sense, as brands with unexpired patents or regulatory exclusivity have no reason to settle for immediate entry. From the brand's perspective, immediate generic entry is the worst-case scenario. That is why nearly 85% of recent settlements contain "restrictions on generic entry," and nearly all of the rest contain restrictions on development or

manufacturing. FY 2016 Overview 2. AB 824 reaches nearly all such settlements, and as such is contrary to the careful balance *Actavis* respected.

The case for conflict preemption here is thus particularly clear. At the heart of each relevant federal law is a delicate balance between competing and often conflicting objectives. And the decision of how to balance competing federal interests receives considerable deference. "The Supreme Court's preemption case law indicates that … a finding of conflict preemption" is particularly likely where—as here—the relevant environment demands "a balance between competing statutory objectives." *Farina* , 625 F.3d at 123; *compare, e.g., Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 348 (2001) (finding preemption where "allowing fraud-on-the-FDA claims under state tort" could "skew[]" the "delicate balance of statutory objectives" in play), *and City of Burbank v. Lockheed Air Terminal Inc.*, 411 U.S. 624, 638-39 (1973) (finding preemption where federal aviation law requires "a delicate balance between safety and efficiency"); *with Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501 (1996) (refusing to find preemption where the "Federal Government" had ***not*** "weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved …, and implemented that conclusion via a specific mandate on manufacturers").

And the conflict between AB 824 and the federal balance goes deeper. The federal patent laws give patent holders the right to grant competitors exclusive licenses—*i.e.*, authorizations allowing competitors to enter the market before patent expiry in exchange for payment. *See* 35 U.S.C. § 261. The Supreme Court has long recognized the validity of such grants, *see, e.g.*, *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 127 (1938), and *Actavis* clearly admonished that such rights should be respected. Indeed, *Actavis* held that the kind of "reverse payments" it addressed could be subject to antitrust attack only after the United States assured the Court that such payments were entirely unlike "an exclusive license," which "is expressly authorized by the Patent Act, in Section 261 of Title 35." Oral Arg. Tr. 3-4, *FTC v. Actavis, Inc.*, No. 12-416 (U.S. Mar. 25, 2013). Nevertheless, AB 824 treats the grant of an exclusive license as presumptively anticompetitive, because it clearly has value for the generic or biosimilar company.

Nor does the conflict end there. Under federal antitrust law, the relevant market (*i.e.*, the market that is considered to determine whether the conduct at issue in fact is anticompetitive) includes all potentially interchangeable products. *See Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). In the pharmaceutical context, that includes all medicines against which a particular drug competes. *See, e.g.*, *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 433-38 (3d Cir. 2016); *Fed. Trade Comm'n v. AbbVie Inc.*, 329 F. Supp. 3d 98 (E.D. Pa. 2018).

Under AB 824, however, the relevant market is presumed to include only the branded drug product and its generic substitutes. *See* Compl. Ex. A § 134002(c). That not only defies reality—medicines often compete against other drugs (both brands and generics) that are not AB-rated in the same class, *see Mylan Pharm.*, 838 F.3d at 435-38—it further tilts the balance toward antitrust and away from patent policy.

And not only are many run-of-the-mill patent settlements presumptively unlawful under AB 824 (in contrast to federal antitrust law, which presumes that a settlement agreement is valid), but it is ***the settling parties' burden*** to overcome that presumption. Nor is overcoming the presumption an easy feat, as it requires showing "either" that "[t]he value received by the [generic/biosimilar] is a fair and reasonable compensation solely for other goods or services that [it] has promised to provide" or that "[t]he agreement has directly generated procompetitive benefits and the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement." Compl. Ex. A § 134002(a)(3). That is exactly the opposite of how the rule of reason—which *Actavis* went out of its way to retain—works. Under the rule of reason, "***the plaintiff*** has the initial burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market," *Ohio v. American Express Co.*, 138 S. Ct. 2274, 2284 (2018) (emphasis added), and the burden does not shift unless and until the plaintiff makes that showing. *See Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 771, 775-76 (1999).

Furthermore, "assumption alone will not do." *Id.* at 775 n.12. Actual "[p]roof that the defendant's activities, on balance, adversely affected competition" is required for the burden to shift to the defendant at all. *Apani Sw., Inc. v. Coca-Cola Enters., Inc.*, 300 F.3d 620, 627 (5th Cir. 2002) (citation omitted). AB 824 casts that standard aside.

The Court's decision in *Actavis* to apply the rule of reason even for antitrust challenges to pharmaceutical patent settlements makes eminent sense. As the Supreme Court held in *Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.*, 472 U.S. 284 (1985), anticompetitive presumptions are appropriate only where conduct at issue "always or almost always tend[s] to restrict competition." *Id.* at 289-90 (citation omitted). And patent settlements—especially those that allow lower-priced generics or biosimilars to enter the market before they otherwise could—obviously do not fit that bill. In all events, even if the Supreme Court's decision to retain the rule of reason in this area did ***not*** make sense, California still would have no license to overrule it. To the contrary, "state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws." *Bonito Boats*, 489 U.S. at 152. While California may prefer a different set of balances than the one the federal government has struck, that is not a choice the Constitution permits.

C. AB 824's Exorbitant Monetary Penalties Violate the Eighth Amendment Prohibition on Excessive Fines.

The Eighth Amendment prohibits states from imposing "excessive fines." U.S. Const. amend. VIII. In particular, the Excessive Fines Clause ("Excessive bail shall not be required, nor excessivse fines imposed….") prevents the government from levying civil penalties that are disproportionate to the underlying conduct. *United States v. Bajakajian*, 524 U.S. 321, 328-34 (1998); *Austin v. United States*, 509 U.S. 602, 609-10 (1993); *see also WCI, Inc. v. Ohio Dep't of Pub. Safety*, 774 F. App'x 959, 967 (6th Cir. 2019) ("If the fine is intended as a punishment—even if only intended partially as a punishment, and partially for other reasons—the protections of the Eighth Amendment apply."). AB 824 plainly violates that clear constitutional prohibition. *See Timbs v. Indiana*, 139 S. Ct. 682, 686-87 (2019) (holding that Eighth Amendment Excessive Fines Clause applies to the states).

In the Ninth Circuit, a civil fine "is unconstitutionally excessive if" three elements are satisfied: the payment is "to the government"; "constitutes punishment for an offense"; and "is grossly disproportionate to the gravity of the defendant's offense." *Mackby*, 261 F.3d at 829; *see id.* at 830-31 (civil monetary penalty under False Claims Act partially punitive and therefore subject to Excessive Fines Clause). AB 824 inarguably satisfies the first two criteria. Under AB 824, "[e]ach person that violates or assists in the violation of this section shall forfeit and pay to the State of California a civil ***penalty***" of no less than "twenty million dollars ($20,000,000)."

Compl. Ex. A § 134002(e)(1)(A) (emphasis added). Only "the Attorney General," not private parties, may sue to collect that penalty. *Id.* § 134002(e)(1)(B). And the penalty must be "sufficient to deter violations of this section," *id.* § 134002(e)(1)(A), which underscores that it is not merely compensatory. *See, e.g.*, *Sabri Props, LLC v. City of Minneapolis*, No. 18-cv-3098 (MJD/HB), 2019 WL 2052597, at *3 (D. Minn. May 9, 2019) ("In the excessive-fines context, however, a fine may constitute punishment when, for example, it does not serve a remedial purpose such as replacing revenue lost by the government," but instead seeks (even in part) to deter wrongdoing.). In sum, AB 824's penalty is clearly a "fine" within the meaning of the Excessive Fines Clause. *See Mackby*, 261 F.3d at 829-31.

AB 824's penalty is just as clearly excessive. A penalty is excessive within the meaning of the Eighth Amendment when "it is grossly disproportional to the gravity of a defendant's offense." *Bajakajian*, 524 U.S. at 334. And while "[t]here is no test for gross disproportionality," *United States v. Altareb*, 758 F. App'x 116, 122 (2d Cir. 2018), the Ninth Circuit "typically 'consider[s] four factors in weighing the gravity of the defendant's offense: (1) the nature and extent of the [offense], (2) whether the violation was related to other illegal activities, (3) the other penalties that may be imposed for the violation, and (4) the extent of the harm caused.'" *United States v. $132,245.00 in U.S. Currency*, 764 F.3d 1055, 1058 (9th Cir. 2014) (quoting *United States v. $100,348.00 in U.S. Currency*, 354 F.3d 1110, 1122 (9th

Cir. 2004)). Each of those factors points in the same direction here—even the minimum penalty the statute imposes is grossly disproportional.

Start with the nature of the conduct that triggers the penalty. AB 824 punishes the act of entering into a settlement agreement to resolve a patent dispute. Unlike fraud or acts of violence, settling a patent dispute is far afield from *malum in se* activity. *Actavis* itself expressly "recognize[d] the value of settlements" in the pharmaceutical context. 570 U.S. at 153-54 ("[S]ettlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit."); *see also Williams v. First Nat'l Bank of Pauls Valley*, 216 U.S. 582, 595 (1910) ("Compromises of disputed claims are favored by the courts; and, presumptively, the parties to the compromise in question possessed the right to thus adjust their differences." (citations omitted)). Nor is there any suggestion that run-of-the-mill patent settlements are "related to other illegal activities." *$132,245.00 in U.S. Currency*, 764 F.3d at 1058. Indeed, if they were, one imagines that the Justice Department (to which all settling parties must disclose the terms of their agreement) would have filed countless suits alleging rampant illegality. Yet that has not happened, and will not in the future. The first two factors thus confirm that this is not an area that calls for sweeping monetary penalties.

The final two factors reinforce that conclusion. As *Actavis* makes evident, most of the settlements that AB 824 reaches are not subject to ***any*** penalties at all

precisely because ordinary patent settlements ***help***, not harm, patients. The result of early generic entry is plainly procompetitive and pro-consumer, as it allows patients access to more affordable medicines long before they would otherwise be available. And, crucially, that result is often not achieved (or even achievable) without settlement. When a patent case proceeds to trial, brand-name manufacturers prevail more than half the time on at least one claim. *See, e.g.*, Lex Machina, *Pharmaceutical Patent Litigation Increases Nearly 30 Percent in 2017: Lex Machina Releases Fourth Hatch-Waxman/ANDA Litigation Report* (May 3, 2018), https://bit.ly/2JnHSxo (generics lost almost 70% of recent such cases). Brand companies also often pursue additional patents that further complicate the real-world prospects of even an ultimately successful patent challenge. Patent settlements are often the only way Americans gain timely access to low-priced medicines.

Despite those obvious and far-reaching benefits, the ***minimum*** penalty AB 824 imposes is $20,000,000, for all "person[s]" that even merely "***assist[] in [a] violation*** of" the statute—***even if the person "has not received anything of value" due to that violation***. Compl. Ex. A § 134002(e)(1)(A) (emphases added). Nor is there any textual criteria for determining what constitutes "assistance" that triggers the $20,000,000-or-more penalty. Under the plain text of the statute, ***all*** persons that assist in a party's violation—not just all "parties" deemed to have violated it—may be punished to the tune of $20,000,000 apiece, even if they gained not a dime as a

result of the violation. It is difficult to fathom a more obvious violation of the Excessive Fines Clause.

And while that is AB 824's most obvious Eighth Amendment violation, it is not the only unconstitutional aspect of AB 824's penalty provisions. The upper limit that the statute authorizes—"three times the value received by the party that is reasonably attributable to the violation of this section," *id.* § 134002(e)(1)(A)—often will amount to hundreds of millions of dollars, which is grossly excessive in relation to the purported anticompetitive harms of a patent settlement that allows a low-priced generic or biosimilar medicine to enter the market prior to patent expiry. That is particularly true with respect to generics and biosimilars. Even the most restrictive settlement agreement usually allows for pre-patent-expiry market entry of a generic or biosimilar competitor. And as *Actavis* explained, "settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition," which redounds "to the consumer's benefit." 570 U.S. at 154.

AB 824 takes none of that into account. Instead, it authorizes crippling monetary penalties on generic and biosimilar manufacturers—and all persons who assist them in settling patent cases—without regard to the strength of the underlying patent or the number of patents that blocked the entry of their less-expensive medicines. The penalties AB 824 imposes are unconstitutional.

D. AB 824's Burden-Shifting Regime Violates AAM's Members Procedural Due Process Rights.

Finally, AAM is also likely to succeed on its procedural due process claim. AB 824 erects a presumption that nearly all patent settlements are anticompetitive and unlawful, it is the defendant's burden to "demonstrate" that the settlement is not in fact anticompetitive. That showing requires proof that "[t]he value received by the [generic] … is a fair and reasonable compensation solely for other goods or services that [it] has promised to provide" or that "[t]he agreement has directly generated procompetitive benefits … [that] outweigh [its] anticompetitive effects." Compl. Ex. A § 134002(a)(3). If the evidence is in equipoise, the defendant loses, and "[e]ach person that violate[d]" the statute (or merely "assist[ed]") is liable for "a civil penalty" of no less than $20 million, and potentially far more. *Id.* § 134002(e)(1)(A).

This burden-shifting regime is contrary to due process. To be sure, most cases analyzing burden-shifting regimes have dealt with criminal prosecutions. But the Supreme Court "has struck down state statutes unfairly shifting the burden of proof" "[i]n civil cases too," particularly where (as here) the statute at issue imposes a form of punishment. *Speiser v. Randall*, 357 U.S. 513, 524 (1958) (citing cases); *cf., e.g.*, *United States v. Morrow*, 368 F. Supp. 2d 863, 866 (C.D. Ill. 2005) (invalidating rebuttable presumption regarding ability to pay child support on the ground that it "impermissibly shifts the burden of persuasion to the defendant … in violation of

the … Due Process Clause"). But even if a state could shift the burden onto the defendant in the first instance without violating due process, the law still would need to ensure that defendants had a meaningful opportunity to disprove that the case for liability has been met.

That requirement is absent here. Although the Act formally allows defendants to establish that their agreements are procompetitive, in practical effect that provision is a dead letter. To take just one example, while the statute gives manufacturers the opportunity to prove that an agreement "directly generated procompetitive benefits … [that] outweigh [its] anticompetitive effects," it also ***presumes*** the existence of those same anticompetitive effects, thus rendering the opportunity effectively meaningless. Compl. Ex. A § 134002(a)(3)(B). That is particularly true given that most patent settlements take years to be fully completed. 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. Under the rule of reason, such considerations would be front and center, and would compel a finding of procompetitiveness. Under AB 824, by contrast, such considerations are given short shrift—if they are given any consideration at all.

Adding insult to injury, AB 824 erects a presumption that the relevant product market includes only the branded drug product and its generic substitutes. *See id.*

§ 134002(c) ("In determining whether the parties to the agreement have met their burden [to rebut the anticompetitiveness presumption], the factfinder shall presume that the relevant product market is that market consisting of the brand or reference drug of the company alleging patent infringement and the drug product of the [generic or biosimilar] company accused of infringement and any other biological product that is licensed as a biosimilar or is an AB-rated generic to the [patented] product."). Under AB 824, in other words, every brand is a monopoly, and therapeutic classes of drugs are full of competing mini-monopolies. That is a stark departure from settled law at the state and federal levels. *See, e.g.*, *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962); Cal. Bus. & Profs. Code § 4073(a).

It also renders the presumption of anticompetitiveness irrebuttable in practice. After all, drugs often compete against brands and generics that are not AB-rated in the same class. AB 824 therefore deprives defendants of the "opportunity to present every available defense," in violation of due process. *Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007) (quoting *Lindsey v. Normet*, 405 U.S. 56, 66 (1972)).

II. AAM's Members Will Suffer Irreparable Harm Absent An Injunction.

AB 824 gives AAM's members a Hobson's choice: Either litigate every patent dispute all the way to judgment or settle and risk massive monetary penalties. *See, e.g.*, Khera Decl. ¶¶ 8-9 (Ex. 1); Kuchii Decl. ¶¶ 6-7 (Ex. 2); Ragan Decl. ¶¶ 9-10 (Ex. 4); Silhavy Decl. ¶ 5 (Ex. 5); Wilson Decl. ¶¶ 10-11 (Ex. 6). Being put to

such an untenable "decision" constitutes irreparable injury all on its own. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992) (finding irreparable injury where plaintiffs faced a "choice" to either "continually violate the [challenged] law and expose themselves to potentially huge liability; or violate the law once as a test case and suffer the injury of obeying the law during the pendency of the proceedings and any further review"). But even if it did not, the harms AB 824 causes would still be textbook irreparable injuries justifying injunctive relief.

As explained, generic and biosimilar manufacturers cannot afford to litigate every patent dispute all the way to judgment. That is particularly true given that success rates are normally no better than fifty-fifty, *see supra* p.9 (citing source), and that most major brand-name drugs are protected by more than one patent. No rational actor would choose to spend years and tens of millions of dollars litigating when the odds are that its efforts will be for naught. Nor would a rational actor risk being forced to prove—on pain of massive monetary penalties of up to three times the value of the settlement—that a settlement that ***will*** generate procompetitive benefits already "***has***." *See* Compl. Ex. A § 134002(a)(3)(B) (emphasis added).

The only rational choice, then, is to sit on the sideline and not file any patent challenges that might provoke litigation. In other words, the inevitable effect of AB 824 will be to freeze AAM's members out of the market almost entirely. *See, e.g.*, Matsuk Decl. ¶¶ 8-10 (Ex. 3). That will cause textbook irreparable injuries. The

scale and suddenness of generics' retreat from the market inevitably will cause blowback, *see, e.g.*, *id.* ¶ 11, leading patients to look elsewhere for their medicines. And as the Ninth Circuit has held time and again, such harm to brand reputation and goodwill is generally considered irreparable. *See, e.g.*, *adidas Am., Inc. v. Skechers USA, Inc.*, 890 F.3d 747, 756-57 (9th Cir. 2018).

The direct economic injuries it will cause are also irreparable. *See, e.g.*, Khera Decl. ¶ 9 (Ex. 1); Kuchii Decl. ¶ 7 (Ex. 2); Matsuk Decl. ¶ 10 (Ex. 3); Silhavy Decl. ¶¶ 5-6 (Ex. 5). To be sure, economic harms usually are not irreparable. But just as "the unsatisfiability of a money judgment can constitute irreparable injury," *Hoxworth v. Blinder, Robinson & Co., Inc.*, 903 F.2d 186, 206 (3d Cir. 1990); *cf. United States ex rel. Taxpayers Against Fraud v. Singer Co.*, 889 F.2d 1327, 1330 (4th Cir. 1989) (injunction appropriate where defendant's assets were "in danger of dissolution and depletion" (citation omitted)), so too can the legal unavailability of obtaining a money judgment in the first place, *see, e.g.*, *Ohio Oil Co. v. Conway*, 279 U.S. 813, 814 (1929) (per curiam) (holding that paying an allegedly unconstitutional tax when state law did not provide a remedy for its return constituted irreparable injury in the event that the statute were ultimately adjudged invalid); *cf. Chamber of Commerce of the U.S. v. Edmondson*, 594 F.3d 742, 770-71 (10th Cir. 2010) ("Imposition of monetary damages that cannot later be recovered for reasons such as sovereign immunity constitutes irreparable injury."). And under the Eleventh

Amendment, private parties are constitutionally prohibited from suing state officials for backward-looking remedies such as money damages or the equivalent. *Frew ex rel. Frew v. Hawkins*, 540 U.S. 431, 437 (2004). Because the Constitution itself deprives AAM's members of any opportunity to recoup the money they would lose as a result of being subjected to this unconstitutional law, no remedy short of an injunction could fully account for the harms they stand to suffer.

The Attorney General likely will argue that AB 824 does not actually prevent AAM's members from settling patent disputes. And, to be sure, only settlements that require a delay in "research, development, manufacturing, marketing, or sales of the [generic] product" and that contain some form of value transfer from the brand to the generic are prohibited under the statute. Compl. Ex. A § 134002(a)(1). But "there are many different sets of circumstances where the two firms will be unable to reach a mutually agreeable settlement without [one]." Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 676 (2004); *see* Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 391 (2010) ("Under certain conditions, without the bargaining tool of a payment … the parties will be unable to reach agreement …."). That is why the overwhelming majority of patent settlements contain at least some transfer of value from the brand to the generic. Basic common sense also explains why nearly all patent settlements

include an agreement by the generic that it will refrain from selling its product for some period of time. Absent settlement, the generic's product would not be able to enter the market until all patents protecting the brand-name drug expired or were invalidated.

In any event, subjecting AAM's members to a law that violates their constitutional rights will also cause irreparable injury on its own. It is well established that the deprivation of constitutional rights "unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality op.); *see also, e.g.*, *Davis v. District of Columbia*, 158 F.3d 1342, 1346 (D.C. Cir. 1998) ("Although a plaintiff seeking equitable relief must show a threat of substantial and immediate irreparable injury, a prospective violation of a constitutional right constitutes irreparable injury for these purposes." (citations omitted)); 11A Charles Alan Wright et al., *Federal Practice & Procedure* § 2948.1 (3d ed.) ("When an alleged deprivation of a constitutional right is involved, … most courts hold that no further showing of irreparable injury is necessary."). That is no less true of the constitutional violations asserted here. *See, e.g.*, *Am. Libraries Ass'n v. Pataki*, 969 F. Supp. 160, 168 (S.D.N.Y. 1997) ("Deprivation of the rights guaranteed under the Commerce Clause constitutes irreparable injury."). In short, AAM's members will suffer irreparable harm absent the requested injunction.

III. The Balance Of Hardships And Public Interest Favor The Injunction.

The public-interest case for enjoining AB 824 is obvious: If the statute goes into effect, the flow of generic and biosimilar medicines will slow—and the hundreds of billions of dollars in savings they bring to patients and the healthcare system will decrease. That is exactly the opposite of what is in the public interest. As explained, both litigation and settlement are inherent in the process by which new generic medicines typically enter the domestic market. Given that many brand-name drugs are protected by multiple patents; that run-of-the-mill ANDAs usually trigger litigation; that the success rate of such litigation is no better than fifty-fifty; and that such litigation typically costs many millions of dollars per side, there is no viable alternative to settlement for bringing low-priced generic medicines to market in a timely manner. The inevitable effect of allowing AB 824 to go into effect will thus be to scuttle patent settlements and the price savings they bring—and the consequences of that will be even more opposed to any conception of the public interest.

If forced to spend millions of dollars litigating ***per patent*** before their products could come to market, generic and biosimilar manufacturers simply will not invest the time and money necessary to develop new medicines in the first place. *See, e.g.*, Matsuk Decl. ¶¶ 8-11 (Ex. 3); Ragan Decl. ¶ 10 (Ex. 4); *see also* Bret M. Dickey & Daniel L. Rubinfeld, *Would the Per Se Illegal Treatment of Reverse Payment*

Settlements Inhibit Generic Drug Investment?, 8 J. COMPETITION L. & ECON. 615, 622 (2012). The inevitable result of taking patent settlements off the table, in other words, would be fewer ANDA and biosimilar filings, fewer patent challenges, fewer low-cost generic and biosimilar medicines on the market, and higher drug prices for patients. *See, e.g.*, Khera Decl. ¶ 9 (Ex. 1); Kuchii Decl. ¶ 7 (Ex. 2); Matsuk Decl. ¶ 10 (Ex. 3); Ragan Decl. ¶¶ 9-10 (Ex. 4); Wilson Decl. ¶¶ 10-11 (Ex. 6); *see also* Sen. Susan Collins, *Working to Keep Lifesaving Medications Affordable* (Sep. 2, 2016) ("[O]ne factor that will help drive down costs for patients is ensuring there is a market for generic competitors."), https://bit.ly/2ORwaLQ. A law that leads to patients paying more for medicines is not a law that is in the public interest.

Making matters worse, allowing AB 824 to go into effect likely will result in increased numbers of patients refraining from taking the medicines they need. "In 2017, patients (both commercially-insured and seniors with Medicare Part D) who were prescribed more expensive brand-name drugs were 2-3 times more likely to abandon their prescriptions, never getting the treatment they need." 2019 Report 14. When Americans abandon their prescriptions because of high prices, they not only "jeopardiz[e] their health," they also "lead[] to higher costs down the road." *Id.* (citation omitted). Again, undermining the public health and raising the cost of healthcare are obviously contrary to any conception of the public interest.

Against those public ills, the harms to the Attorney General will be *de minimis* (if they exist at all). Regardless of how this case is resolved, the Attorney General will still be able to enforce the Cartwright Act, not to mention federal antitrust law. *See generally In re Cipro Cases I & II*, 348 P.3d 845 (Cal. 2015). Granting AAM's requested injunction therefore will not materially affect California's efforts to protect its consumers. Nor will it harm the Attorney General in any other cognizable way, as 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); *see also, e.g.*, *Deja Vu of Nashville, Inc. v. Metro. Gov't of Nashville & Davidson Cty.*, 274 F.3d 377, 400 (6th Cir. 2001) (Where "the plaintiff shows a substantial likelihood that the challenged law is unconstitutional, no substantial harm to others can be said to inhere in its enjoinment.").

Enjoining AB 824 will have no meaningful negative effect on the Attorney General. What enjoining AB 824 will do, though, is help ensure that patients who need access to lower-cost generic and biosimilar medicines are able to obtain them under the federal regulatory and patent system that Congress has created to balance innovation and access to more affordable medicines. It will also ensure that an unconstitutional statute is not enforced. *Gordon v. Holder*, 721 F.3d 638, 653 (D.C. Cir. 2013) ("[E]nforcement of an unconstitutional law is always contrary to the

public interest."). The balance of equities and the public interest decidedly support AAM's request for preliminary injunctive relief.

CONCLUSION

For the foregoing reasons, the Court should grant AAM's motion.

Respectfully submitted,

s/Matthew D. Rowen
MATTHEW D. ROWEN (292292)
Counsel of Record
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue NW
Washington, DC 20004
(202) 389-5000
matthew.rowen@kirkland.com

JAY P. LEFKOWITZ (*phv* forthcoming)
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800
lefkowitz@kirkland.com

Counsel for Plaintiff

November 12, 2019

EXHIBIT 1

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA

ASSOCIATION FOR ACCESSIBLE MEDICINES, Plaintiff, - against - XAVIER BECERRA, in his official capacity as Attorney General of the State of California, Defendant.	Case No.

DECLARATION OF BRIJ KHERA

I, Brij Khera, declare:

1. I am the Executive Vice President and Chief Legal Officer of Zydus Pharmaceuticals (USA) Inc. ("Zydus"). I have held that position for ten (10) years. I am knowledgeable about Zydus's recent and pending litigation activity.

2. Zydus is a corporation organized and existing under the laws of New Jersey that has corporate offices in Pennington, New Jersey and is headquartered in Pennington, New Jersey. Zydus has manufacturing facilities in India.

3. Over the past ten (10) years, Zydus has filed one hundred and thirteen (113) Abbreviated New Drug Applications with Paragraph IV certifications. In seventy-eight (78) of those cases, the relevant patent-holder responded to Zydus's filing by suing Zydus for patent infringement.

4. Five (5) of those lawsuits were litigated to judgment. Of those, Zydus prevailed in three (3). The patent-holder prevailed in the remaining two (2).

5. Forty-eight (48) of those lawsuits resulted in settlement.

6. Based on settlement Zydus launched: Esomeprazole delayed-release capsules; Mesalamine delayed-release tablets, 800 mg; Tadalafil tablets; and Venlafaxine extended-release capsules.

7. In addition to those already-completed infringement suits, Zydus is currently a defendant in the patent-infringement lawsuits set forth on the Annex hereto that were prompted by its filing of an Abbreviated New Drug Applications with Paragraph IV certification.

8. Under any scenario, Zydus will be injured by operation of AB 824. In light of the massive monetary penalties AB 824 exposes and the uncertainty it creates, Zydus likely will be forced to litigate every one of those pending patent-infringement lawsuits to judgment, even if a procompetitive settlement agreement could be reached. Yet even prevailing in such litigation will not necessarily allow Zydus to bring its generic medicines to market.

9. Moreover, Zydus is currently developing a number of new generic medicines. Absent AB 824, Zydus likely would file Abbreviated New Drug Applications with Paragraph IV certifications for many of those new medicines. Yet in light of AB 824, Zydus now likely will stay its hand and simply stay off the market

until the relevant patents all expire, lest it be forced to choose between being exposed to AB 824's sweeping penalties and spending millions of dollars and many years challenging every patent covering the relevant medicine all the way judgment. AB 824 will therefore cost Zydus millions of dollars no matter what choices it makes going forward.

I declare under penalty of perjury that the foregoing is true and correct. Executed in Pennington, New Jersey on October 29, 2019.

Brij Khera

Annex

Current Litigations

- Levomilnacipran Extended-Release Capsules (Forest v. Zydus 2:17-cv-10330)
- Carbidopa and Levodopa Extended-Release Capsules (Impax v. Zydus 2:17-cv-13476)
- Vortioxetine Tablets (Lundbeck and Takeda v. Zydus 1:18-cv-00088-LPS (consolidated)
- Lenalidomide Capsules (Celgene v. Zydus 2:17-cv-02528-SDW-LDW)
- Macitentan Tablets (Actelion v. Zydus 3:18-cv-01397-FLW-LHG)
- Dapagliflozin Tablets (AstraZeneca 1:18-cv-00664-RGA)
- Apremilast Tablets (Celgene v. Zydus 3:18-cv-11267)
- Tavaborole Topical Solution (Anacor v. Zydus 1:18-cv-01673-UNA)
- Canagliflozin Tablets (Mitsubishi v. Zydus 3:17-cv-05302-FLW-DEA)
- Canagliflozin and Metformin Hydrochloride Tablets (Mitsubishi v. Zydus 3:17-cv-05319-MAS-LHG)
- Empagliflozin Tablets (Boehringer v. Zydus 1:18-cv-01689-CFC-SRF (consolidated))
- Empagliflozin and Metformin Hydrochloride Tablets (Boehringer v. Zydus 1:18-cv-01689-CFC-SRF (Consolidated))
- Empagliflozin and Linagliptin Tablets (Boehringer v. Zydus 1:18-cv-01689-CFC (consolidated))
- Palbociclib Capsules (Pfizer v. Zydus 1:19-cv-00760-CFC)
- Eluxadoline Tablets (Allergan v. Zydus 1:19-cv-01727-RGA)
- Sitagliptin Tablets (Merck v. Zydus 1:19-cv-00314-RGA)
- Sitagliptin and Metformin Hydrochloride Tablets (Merck v. Zydus 1:19-cv-00314-RGA)
- Sitagliptin and Metformin Extended-Release Tablets (Merck v. Zydus 1:19-cv-00314-RGA)
- Fingolimod Capsules (Novartis v. Zydus 1:18-cv-01043-LPS)
- Dimethyl Fumarate Delayed-Release Capsules (Biogen v. Zydus 1:17-cv-00823-LPS (consolidated))
- Cinacalcet (Amgen Inc. v. Zydus, Defendant-Cross-Appellants 18-2414, 19-1086)
- Plerixafor (Genzyme v. Zydus 18-2362)
- Tofacitnib (Pfizer v. Zydus 17-158 (LPS) consolidated)
- Brexpiprazole (Otsuka v. Zydus 1:99-mc-09999)

EXHIBIT 2

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA

ASSOCIATION FOR ACCESSIBLE MEDICINES, Plaintiff, - against - XAVIER BECERRA, in his official capacity as Attorney General of the State of California, Defendant.	Case No.

DECLARATION OF CRAIG KUCHII

I, Craig Kuchii, declare:

1. I am the Head of Intellectual Property for Sun Pharmaceuticals Industries Inc. and Taro Pharmaceuticals USA, Inc. (collectively "SunTaro"). I have held that position for more than two (2) years. I am knowledgeable about SunTaro's recent and pending patent litigation activity.

2. Sun Pharmaceuticals Industries Inc. is a corporation organized and existing under the laws of Michigan that has corporate offices and is headquartered in Princeton, New Jersey. Taro Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of New York that has corporate offices and is headquartered in Hawthorne, New York.

3. Since January 1, 2014, SunTaro has filed 90 Abbreviated New Drug

Applications or 505(b)(2) applications with Paragraph IV certifications. In 56 of those cases, the relevant patent-holder responded to such filing by suing the filing company for patent infringement.

4. 3 of those lawsuits were litigated to judgment. Of those, SunTaro prevailed in only 1 case. The patent-holder prevailed in the others.

5. 31 of those lawsuits resulted in settlements under which SunTaro received a licensed entry date earlier than the last to expire Orange Book-listed patent.

6. SunTaro will be injured by operation of AB 824 and its ability to bring lower cost generics to the market earlier than patent expiry will be hampered. In light of the massive monetary penalties AB 824 exposes and the uncertainty it creates, SunTaro likely will be forced to incur significant costs and risk litigating even cases with uncertain outcomes to judgment, even if a procompetitive settlement agreement could otherwise be reached. In the event that SunTaro is unsuccessful in the litigation, not only would SunTaro have wasted millions in development costs and litigation fees, but ultimately the consumers would suffer because generic entry would be delayed until patent expiry.

7. Moreover, SunTaro is currently developing a number of new generic/biosimilar medicines. Absent AB 824, SunTaro likely would file Abbreviated New Drug Applications with Paragraph IV certifications for many of

those new medicines and would likely be able to enter the market at some point prior to patent expiry. Yet in light of AB 824, SunTaro now likely will stay its hand on many products and simply stay off the market until the relevant patents all expire, lest it be forced to choose between being exposed to AB 824's sweeping penalties and spending millions of dollars and many years challenging every patent covering the relevant medicine all the way to judgment. AB 824 will therefore cost SunTaro millions of dollars and harm consumers by delaying generic entry.

I declare under penalty of perjury that the foregoing is true and correct. Executed in Princeton, New Jersey on October 31, 2019.

Craig Kuchii

EXHIBIT 3

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA

ASSOCIATION FOR ACCESSIBLE MEDICINES, Plaintiff, - against - XAVIER BECERRA, in his official capacity as Attorney General of the State of California, Defendant.	Case No.

DECLARATION OF ROBERT MATSUK

I, Robert Matsuk, declare:

1. I am the President — North America of Glenmark Pharmaceuticals Inc., USA ("Glenmark"). I have held that position for five years. I am knowledgeable about Glenmark's recent and pending litigation activity.

2. Glenmark is a corporation organized and existing under the laws of Delaware and has corporate offices in Mahwah, New Jersey. Glenmark has a manufacturing facility in Monroe, North Carolina.

3. Glenmark has developed certain expertise in the development, sales and marketing of generic pharmaceutical products in the United States.

4. Glenmark allocates a finite amount of funds specifically earmarked for the research and development of new generic products.

5. A number of the Abbreviated New Drug Applications ("ANDA") that Glenmark files for the generic products it develops contain Paragraph IV certifications that have subjected Glenmark to patent infringement suits. Glenmark evaluates each suit and determines when it is in its best interest to settle and when to litigate.

6. Glenmark will be injured by operation of AB 824. In light of the massive monetary penalties AB 824 imposes and the uncertainty it creates, Glenmark anticipates that it will be forced to litigate more (if not most) patent-infringement lawsuits to judgment, even if procompetitive settlement agreements could be reached.

7. AB 824 would require Glenmark to add significant funds to its litigation budget in order to litigate more (if not most) patent infringement lawsuits brought on by its filing an ANDA that contains a PIV certification.

8. Because Glenmark does not have a limitless pool of funds for the research and development of generic products, an increase in the litigation budget will reduce the overall research and development budget for new generic products.

9. Any reduction in the overall research and development budget for new generic products will mean that Glenmark will develop fewer new generic products.

10. If Glenmark develops fewer new generic products, it will be harmed financially, and the public will be harmed by having fewer products to choose from

and therefore less generic competition.

11. Absent AB 824, Glenmark likely would continue to file Abbreviated New Drug Applications with Paragraph IV certifications at the same rate as in the past.

I declare under penalty of perjury that the foregoing is true and correct. Executed in Mahwah , New Jersey on November 4, 2019.

Robert Matsuk
President – North America

EXHIBIT 4

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA

ASSOCIATION FOR ACCESSIBLE MEDICINES, Plaintiff, - against - XAVIER BECERRA, in his official capacity as Attorney General of the State of California, Defendant.	Case No.

DECLARATION OF COLMAN B. RAGAN, ESQ.

I, Colman B. Ragan declare:

1. My current title is Vice President & General Counsel, North America Intellectual Property Litigation at Teva Pharmaceuticals USA, Inc. ("Teva"). I have held that position for almost two years, and have been with Teva or predecessor companies for almost seven years. I am knowledgeable about Teva's recent and pending patent litigation activity.

2. Teva is a corporation organized and existing under the laws of Delaware with current U.S. headquarters in North Wales, Pennsylvania. Teva and its affiliates also have offices—and operate manufacturing, distribution, and/or research-and-development sites—in a number of other U.S. states, including California.

3. Since acquiring the Actavis generics business from Allergen plc in August 2016, Teva and its affiliates have filed at least seventy (70) total Abbreviated New Drug Applications ("ANDAs") with Paragraph IV certifications and abbreviated Biologics License Applications ("ABLAs"). In the vast majority of those cases, the relevant patent-holder responded to Teva's filing by suing Teva for patent infringement.

4. Since August 2016, Teva has litigated, to either a first-instance judgment and/or an appellate judgment, about sixty (60) litigations relating to Paragraph IV ANDAs and ABLAs that were either (a) pending as of August 2016 or (b) resulted from Paragraph IV ANDAs or ABLAs filed after August 2016.

5. Of those sixty (60) litigations, Teva prevailed 37 times either at the district court and/or on appeal. I limited this number to cases in which Teva prevailed on all then-asserted patents, whether in a preliminary injunction, a full trial at the district court, and/or an appeal on the same Paragraph IV ANDA or ABLA. Because wins at various stages of litigation were counted in my analysis, some of the 37 wins concerned the same product and litigation, and the total number of products on which Teva prevailed was fewer than 37.

6. Of those sixty (60) litigations referred to above, the patent-holder prevailed on at least one claim of one asserted patent thirty-one (31) times. This number includes any instance where Teva lost on at least one claim of one asserted

patent. Therefore, instances where Teva prevailed on one or more patents, but ultimately did not clear all asserted patents, were counted as "losses" in my analysis. This number also includes instances where Teva lost in a preliminary injunction, a full trial at the district court, and/or an appeal on the same Paragraph IV ANDA or ABLA for which it prevailed at some other stage of the litigation.

7. For any lawsuits that were either (a) pending as of August 2016 or (b) arose from the filing of a Paragraph IV ANDA or ABLA after August 2016, seventy-seven (77) of those lawsuits resulted in settlement.

8. In addition to those already-completed infringement suits, Teva is currently a defendant in more than fifty (50) currently pending patent-infringement lawsuits that were prompted by its filing of a Paragraph IV ANDA or ABLA.

9. Teva will be injured by AB 824. In light of AB 824's massive monetary penalties, as well as the uncertainty it will create, Teva could be forced to either litigate many of those pending patent-infringement lawsuits to judgment, even if a procompetitive settlement agreement could otherwise be reached, or withdraw its applications rather than incur the expense and uncertainty of litigation.

10. Moreover, Teva is currently developing a number of new generic/biosimilar medicines, and files dozens of new ANDAs and ABLAs each year. Absent AB 824, Teva likely would file Paragraph IV ANDAs or ABLAs for

many of these new medicines. Yet in light of AB 824, Teva will likely need to revisit its portfolio of Paragraph IV ANDAs and ABLAs that challenge innovator patents, and will likely decide not to bring some of these challenges (or file some of these applications) in the first place, because AB 824 will make it difficult, if not impossible, to settle the ensuing litigations.

I declare under penalty of perjury that the foregoing is true and correct. Executed in Parsippany, New Jersey on November 7, 2019.

Colman B. Ragan
Vice President & General Counsel
North America IP Litigation
Teva Pharmaceuticals USA, Inc.

EXHIBIT 5

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA

ASSOCIATION FOR ACCESSIBLE MEDICINES, Plaintiff, - against - XAVIER BECERRA, in his official capacity as Attorney General of the State of California, Defendant.	Case No.

DECLARATION OF JACK C. SILHAVY

I, Jack C. Silhavy, declare:

1. I am the General Counsel of Fresenius Kabi USA, LLC ("Fresenius Kabi"), a position I have held for eight years. I am knowledgeable about Fresenius Kabi's recent and pending litigation activity.

2. Fresenius Kabi is a limited liability company organized and existing under the laws of Delaware, headquartered in Lake Zurich, Illinois. Fresenius Kabi has manufacturing facilities in Illinois, New York, and North Carolina.

3. Over the past several years, Fresenius Kabi has filed numerous Abbreviated New Drug Applications with Paragraph IV certifications. In the vast majority of those cases, the brand manufacturer responded to Fresenius Kabi's filing by suing Fresenius Kabi for patent infringement.

4. The majority of these lawsuits have resulted in settlement. Although the terms of many of these settlements are confidential, these settlements generally permit Fresenius Kabi to launch medicines years before patent expiration. The brand manufacturers relevant to these medicines were in most instances organized and headquartered outside the State of California, and the agreements were governed by the laws of other states.

5. Under any scenario, Fresenius Kabi will be injured by operation of AB 824. In light of the massive monetary penalties AB 824 imposes and the uncertainty it creates, Fresenius Kabi likely would expect to be forced to litigate every pending patent-infringement lawsuit to judgment, even if a settlement agreement allowing early entry (and therefore one that is clearly procompetitive) could be reached. And even prevailing in such litigation will not necessarily allow Fresenius Kabi to bring its generic and biosimilar medicines to market without risk. For instance, brand manufacturers often obtain patents that they are not required to list with the FDA (for example, patents covering manufacturing processes for medicines), which they can still assert following the generic company's launch of its medicine. Unless Fresenius Kabi can obtain certainty of being free of all future patent litigation via settlement, as is often the case when patent settlements are reached, Fresenius Kabi remains subject to a such a large risk of patent damages that it may decide not even to launch its product.

6. Fresenius Kabi is currently developing a number of new generic and biosimilar medicines. Absent AB 824, Fresenius Kabi likely would file Abbreviated New Drug Applications with Paragraph IV certifications and abbreviated Biologics License Applications for many of those new medicines. Yet in light of AB 824, Fresenius Kabi in many instances will have to consider whether to stay its hand and undertake to simply stay off the market until the relevant patents all expire, lest it be forced to choose between being exposed to AB 824's sweeping penalties and spending millions of dollars and many years challenging every patent covering the relevant medicine all the way to judgment. And for other new medicines, Fresenius Kabi will elect not to proceed with development of generic and biosimilar medicines at all due to the cost and uncertainty of patent litigation, which is on top of several million dollars of research and development costs (if not more) for each generic and biosimilar medicine. AB 824 will therefore cost Fresenius Kabi millions of dollars no matter what choices it makes going forward. Additionally, knowing this, brand companies can be expected to seek even more patents and thereby extend their monopolies knowing that the generics face this dilemma.

I declare under penalty of perjury that the foregoing is true and correct. Executed in Lake Zurich, Illinois on November 12, 2019.

Jack C. Silhavy

EXHIBIT 6

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA

ASSOCIATION FOR ACCESSIBLE MEDICINES, Plaintiff, - against - XAVIER BECERRA, in his official capacity as Attorney General of the State of California, Defendant.	Case No.

DECLARATION OF MYLAN WITNESS

I, Anne Wilson, declare:

1. I am a member of the Government Affairs team of Mylan Inc. (together with its subsidiaries, "Mylan"). I have held that position for over four years. I am knowledgeable about both California's recent enactment of Assembly Bill 824 ("AB 824") and Mylan's recent and pending patent litigation activity.

2. Mylan is a leader in the global pharmaceutical industry and develops, licenses, manufactures, markets, and distributes generic, branded generic, and specialty pharmaceuticals. Mylan is committed to setting new standards in health care, and our mission is to provide the world's 7 billion people access to high quality medicine.

3. Mylan has pharmaceutical manufacturing facilities in numerous

locations throughout the United States, including West Virginia, Texas, Vermont, and Puerto Rico.

4. Over the past six years, Mylan has filed over 100 Abbreviated New Drug Applications ("ANDAs") with Paragraph IV certifications. In over 75% of those ANDA filings, the relevant patent-holder responded to Mylan's filing by suing Mylan for patent infringement.

5. From January 1, 2014 through the present, Mylan litigated over 20 ANDA cases through a final non-appealable judgment. Of those, Mylan prevailed about 55% of the time and the patent holder prevailed about 45% of the time.

6. From January 1, 2014 through the present, Mylan settled over 70 ANDA cases prior to receiving a final non-appealable judgment. Those settlements provide Mylan with a license and/or covenant not to sue that allows Mylan to come to market with its generic medicine prior to the expiration of the last expiring Orange Book-listed patent. Collectively, these settlements have shortened the brand's patent exclusivity by over 350 years.

7. In addition to already-completed infringement suits, Mylan is currently a defendant in at least twenty-five patent-infringement lawsuits that were prompted by its filing of an ANDA with a paragraph IV certification.

8. Settlements are often the only way a generic version of a medicine can enter the market prior to patent expiration. There are cases where certain settling

parties are able to reach a settlement which may permit them an early entry before patent expiration while other parties elect to not settle, lose their litigations, and are enjoined until patent expiration. For example, with respect to Sensipar® (cinacalcet), Mylan and certain other generics settled with Amgen prior to trial, while Zydus elected to continue to litigate. Zydus lost. And, while that decision is on appeal, Zydus is currently enjoined until patent expiration. Another example is Frova® (frovatriptan). In that case, Mylan went to trial but settled before the District Court issued a decision. But for Mylan entering into that agreement, Mylan would have been enjoined until patent expiration. Other examples include: Livalo® (pitavastatin), Ofirmev® (acetaminophen), Seroquel XR (quetiapine), Multaq® (dronedarone), and Treanda® (bendamustine). The list of such occurrences is extensive.

9. Settlements are also a way for a party that loses at the District Court to avoid being enjoined until the expiration of the patent. Parties can reach a settlement while the case is on appeal that permits market entry prior to patent expiration. An example where this occurred is with respect to Savella® (milnacipran). In that case, Mylan lost at the District Court but subsequently reached a settlement agreement during the pendency of the appeal which permits market entry prior to patent expiration.

10. The recently enacted AB 824 will make it more difficult for Mylan to

settle patent cases. For example, a plaintiff may interpret AB 824 to presume to be anticompetitive, a settlement in which Mylan is given a license to enter even before patent expiration because the license includes additional terms to the right to entry. The risk of a lawsuit may deter both the brand company and Mylan from entering into the settlement.

11. Because of a diminished ability to obtain early entry due to the enactment of AB 824, Mylan will need to reconsider decisions to bring generic drugs and biosimilar products to market. In particular, if Mylan's ability to settle patent cases is constrained, Mylan will need to reconsider its product pipeline and strategy associated with its products. As a result, Mylan is likely to bring fewer generic and biosimilar products to market compared to when its ability to settle is not impeded.

I declare under penalty of perjury that the foregoing is true and correct. Executed in Washington, D.C. on November 8, 2019.

Anne Wilson

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA

ASSOCIATION FOR ACCESSIBLE MEDICINES, Plaintiff, - against - XAVIER BECERRA, in his official capacity as Attorney General of the State of California, Defendant.	Case No.

[PROPOSED] ORDER GRANTING PRELIMINARY INJUNCTION

Upon consideration of Plaintiff's Motion for Preliminary Injunction, the supporting Memorandum of Law, the Complaint, the Declarations of Brij Khera, Craig Kuchii, Robert Matsuk, Colman B. Ragan, Esq., Jack C. Silhavy, and Anne Wilson, and the record as a whole, the Court hereby finds that: (1) Plaintiff is likely to succeed on the merits of its claims for declaratory and injunctive relief; (2) Plaintiff and its members will suffer irreparable harm if Defendant is not immediately enjoined from implementing or enforcing AB 824; (3) granting the requested preliminary injunction will not substantially injure Defendant, and the balance of hardships favors Plaintiff; and (4) granting the requested preliminary

injunction will further the public interest. Plaintiff's Motion for Preliminary Injunction is therefore GRANTED.

Accordingly, Defendant, along with all of his officers, agents, employees, attorneys, and all persons in active concert or participation who receive actual notice of this Order, are enjoined from implementing and enforcing AB 824 against Plaintiff, its members, or their agents and licensees.

Because Defendant will suffer no cognizable injury during the pendency of this preliminary injunction, no bond is required.

IT IS SO ORDERED.

Date:
Time:

_____
United States District Judge