

1 XAVIER BECERRA, State Bar No. 118517
 Attorney General of California
 2 EMILIO VARANINI, State Bar No. 163952
 KARLI EISENBERG, State Bar No. 281923
 3 Supervising Deputy Attorneys General
 JACQUELINE PALMA MALAFA, State Bar No. 325328
 4 Deputy Attorney General
 300 S. Spring Street
 5 Los Angeles, CA 90013
 Telephone: (213) 269-6389
 6 Fax: (213) 731-2119
 E-mail: Jacqueline.Malafa@doj.ca.gov
 7 *Attorneys for Defendant Xavier Becerra, in his*
official capacity as Attorney General of the State of
 8 *California*

9 IN THE UNITED STATES DISTRICT COURT
 10 FOR THE EASTERN DISTRICT OF CALIFORNIA

11
 12
 13 **ASSOCIATION FOR ACCESSIBLE**
 14 **MEDICINES,**
 15 Plaintiff,
 16 v.
 17 **XAVIER BECERRA, IN HIS OFFICIAL**
 18 **CAPACITY AS ATTORNEY GENERAL**
 19 **OF THE STATE OF CALIFORNIA,**
 20 Defendant.

2:20-cv-01708-TLN-DB

**DEFENDANT’S OPPOSITION TO
 PLAINTIFF’S MOTION FOR A
 PRELIMINARY INJUNCTION**

Date: October 29, 2020
 Time: 2:00 p.m.
 Courtroom: 2
 Judge: The Honorable Troy L. Nunley
 Action Filed: August 25, 2020

21
 22
 23
 24
 25
 26
 27
 28

TABLE OF CONTENTS

	Page
INTRODUCTION	1
FACTUAL BACKGROUND	2
STANDARD OF REVIEW	4
ARGUMENT	4
I. AAM Does Not Have Standing.....	4
II. AAM Is Not Likely to Succeed on the Merits	7
A. AB 824 Does Not Violate the Commerce Clause.....	7
1. AAM’s Pre-Enforcement, As-Applied Dormant Commerce Clause Claim Is Not Constitutionally Ripe.....	7
2. AAM’s Dormant Commerce Clause Claim Is Not Prudentially Ripe	8
3. AAM’s Dormant Commerce Clause Fails on the Merits	9
B. AB 824 Is Not Preempted.....	13
1. AB 824 Does Not Conflict with Patent Law.....	13
2. AB 824 Is Not Preempted by Actavis	14
3. AB 824 Does Not Conflict with the Hatch-Waxman Act	15
4. AB 824 Does Not Conflict with the BPCIA	16
C. AB 824 Does Not Violate the Prohibition on Excessive Fines	16
1. AAM’s Excessive Fines Claim Is Not Ripe	17
2. AAM’s Excessive Fines Claim Fails.....	17
D. AB 824 Does Not Violate Due Process	18
III. AAM Has Not Demonstrated Imminent and Irreparable Harm.....	19
IV. Enjoining AB 824 Would Not Be in the Public Interest.....	20
CONCLUSION	20

TABLE OF AUTHORITIES

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Page

CASES

AAM v. Becerra
Mem. & Order on Pl.’s Mot. for Prelim. Inj., No. 2:19-cv-02281, 2019 WL 7370421 (E.D. Cal. Dec. 31, 2019) *passim*

AAM v. Becerra
No. 20-15014, 2020 WL 4251776 (9th Cir. July 24, 2020)..... 4, 6

Amgen Inc. v. Sandoz Inc.
877 F.3d 1315 (Fed. Cir. 2017) 16

Ass’n des Eleveurs de Canards et d’Oies du Quebec v. Harris
729 F.3d 937 (9th Cir. 2013)..... 12

Ass’n for Accessible Meds. v. Frosh
887 F.3d 664 (4th Cir. 2018)..... 12

Baldwin v. G.A.F. Seelig
294 U.S. 511 (1935)..... 12

Bland v. Fessler
88 F.3d 729 (9th Cir. 1996)..... 5

Brand Name Prescription Drugs
123 F.3d 599 (7th Cir. 1997)..... 10

Buckman Co. v. Plaintiffs’ Legal Committee
531 U.S. 341 (2001)..... 14

California v. ARC Am. Corp.
490 U.S. 93 (1989).....13, 15

Chinatown Neighborhood Ass’n v. Harris
794 F.3d 1136 (9th Cir. 2015).....11, 13

Clapper v. Amnesty Int’l USA
568 U.S. 398 (2013).....5, 6, 7

Clark v. City of Seattle
899 F.3d 802 (9th Cir. 2018)..... 7

Cotto Waxo Co. v. Williams
46 F.3d 790 (8th Cir. 1995)..... 11

TABLE OF AUTHORITIES
(continued)

		<u>Page</u>
1		
2		
3	<i>Daniels Sharpsmart, Inc. v. Smith</i>	
4	889 F.3d 608 (9th Cir. 2018).....	9, 12
5	<i>Doe v. Reed</i>	
6	561 U.S. 186 (2010).....	16
7	<i>Drakes Bay Oyster Co. v. Jewell</i>	
8	747 F.3d 1073 (9th Cir. 2014).....	20
9	<i>Farina v. Nokia Inc.</i>	
10	625 F.3d 97 (3d Cir. 2010).....	13
11	<i>FTC v. Actavis</i>	
12	2013 WL 417736 (Jan. 29, 2013).....	15
13	<i>FTC v. Actavis</i>	
14	570 U.S. 136 (2013).....	13, 14, 15
15	<i>Gill v. Whitford</i>	
16	138 S. Ct. 1916 (2018).....	20
17	<i>Golden v. Zwickler</i>	
18	394 U.S. 103 (1969).....	9
19	<i>Gonzalez v. CarMax Auto Superstores, LLC</i>	
20	840 F.3d 644 (9th Cir. 2016).....	18
21	<i>Healy v. Beer Inst.</i>	
22	491 U.S. 324 (1989).....	9, 10, 11
23	<i>Heath Consultants, Inc. v. Precision Instruments, Inc.</i>	
24	527 N.W.2d 596 (Neb. 1995).....	10
25	<i>Hunt v. Wash. Apple Advertising Comm’n</i>	
26	432 U.S. 333 (1977).....	4
27	<i>IMS Health Inc. v. Mills</i>	
28	616 F.3d 7 (1st Cir. 2010).....	10
	<i>In re Cipro Cases I & II</i>	
	348 P.3d 845 (Cal. 2015).....	<i>passim</i>
	<i>In re Lorazepam</i>	
	295 F. Supp. 3d 30 (D.D.C. 2003).....	10

TABLE OF AUTHORITIES

(continued)

	<u>Page</u>
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
26	
27	
28	

<i>King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.</i> 791 F.3d 388 (3d Cir. 2015).....	13
<i>Knevelbaard Dairies v. Kraft Foods, Inc.</i> 232 F.3d 979 (9th Cir. 2000).....	9
<i>Lujan v. Defenders of Wildlife</i> 504 U.S. 555 (1992).....	4
<i>Maldonado v. Morales</i> 556 F.3d 1037 (9th Cir 2009).....	7, 8
<i>Maryland v. King</i> 567 U.S. 1301 (2012).....	20
<i>MD/DC/DE Broadcasters Ass’n v. FCC</i> 236 F.3d 13 (D.C. Cir. 2001).....	20
<i>Medtronic, Inc. v. Lohr</i> 518 U.S. 470 (1996).....	13
<i>Monarch Content Mgmt. LLC v. Ariz. Dep’t of Gaming</i> 971 F.3d 1021 (9th Cir. 2020).....	11
<i>Nat’l Audubon Soc’y, Inc. v. Davis</i> 307 F.3d 835 (9th Cir. 2002).....	7
<i>Nat’l Elec. Mfrs. Ass’n v. Sorrell</i> 272 F.3d 104 (2d Cir. 2001).....	11
<i>Nevada v. Hicks</i> 533 U.S. 353 (2001).....	18
<i>NIFLA v. Harris</i> 839 F.3d 823 (9th Cir. 2016).....	8, 9
<i>Oklevueha Native American Church of Hawaii v. Holder</i> 676 F.3d 829 (9th Cir. 2012).....	8, 9
<i>Olstad v. Microsoft Corp.</i> 700 N.W.2d 139 (Wisc. 2005).....	10
<i>Pharm. Research & Mfrs. of Am. v. Walsh</i> 538 U.S. 644 (2003).....	12

TABLE OF AUTHORITIES

(continued)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Page

Polk Bros., Inc. v. Forest City Enters., Inc.
776 F.2d 185 (7th Cir. 1985)..... 19

RLH Indus., Inc. v. SBC Commc’ns, Inc.
35 Cal. Rptr. 3d 469 (2005)..... 10

Rocky Mountain Farmers Union v. Corey
730 F.3d 1070 (9th Cir. 2013).....9, 11, 12

Rosenblatt v. City of Santa Monica
940 F.3d 439 (9th Cir. 2019)..... 7, 10

Sabri v. United States
541 U.S. 600 (2004)..... 12

Sam Francis Found. v. Christies, Inc.
784 F.3d 1320, 1322 (9th Cir. 2015) 12

San Diego Cnty. Gun Rights v. Reno
98 F.3d 1121 (9th Cir. 1996).....5, 6, 8

Sierra Forest Legacy v. Sherman
646 F.3d 1161 (9th Cir. 2011)..... 20

SmithKline v. King Drug
2016 WL 5765167 (Oct. 3, 2016)..... 13

Solem v. Helm
463 U.S. 277 (1983)..... 18

Speiser v. Randall
357 U.S. 513 (1958)..... 19

State ex rel. French v. Overstock.com. Inc.
2019 WL 2714835 (Del. Super. Ct. June 28, 2019) 18

State v. Sterling Theatres Co.
394 P.2d 226 (Wash. 1964) 10

Susan B. Anthony List v. Driehaus
573 U.S. 149 (2014)..... 8

Thomas v. Anchorage Equal Rights Com’n
220 F.3d 1134 (9th Cir. 2000).....7, 8, 9

TABLE OF AUTHORITIES

(continued)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Page

Timbs v. Indiana
139 S. Ct. 682 (2019)..... 18

U.S. v. \$132,245.00 in U.S. Currency
764 F.3d 1055 (9th Cir. 2014)..... 17

United States v. Bajakajian
524 U.S. 321 (1998)..... 18

United States v. Microsoft Corp.
253 F.3d 34 (D.C. Cir. 2001)..... 19

Upjohn Co. v. Mova Pharm. Corp.
225 F.3d 1306 (Fed. Cir. 2000)..... 14

Valley Drug Co. v. Geneva Pharm., Inc.
344 F.3d 1294 (11th Cir. 2003)..... 19

Water-Pierce Oil Co. v. Tex.
212 U.S. 86 (1909)..... 18

Winter v. Natural Res. Def. Council, Inc.
555 U.S. 7 (2008)..... 4, 20

Younger v. Jensen
605 P.2d 813 (Cal. 1980)..... 10

STATUTES

California Business & Professions Code
§ 16750..... 18

§ 16750(a)..... 17

§ 16752..... 17

TABLE OF AUTHORITIES
(continued)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Page

California Health & Safety Code

§ 134000(c).....	10
§ 134002.....	17
§ 134002(a)(1)	2, 3, 10
§ 134002(a)(1)(A)-(B)	3
§ 134002(a)(1)(B).....	4
§ 134002(a)(2)(C).....	3
§ 134002(a)(3)(A)-(B)	3
§ 134002(d)(2).....	20
§ 134002(e)(1)(A).....	18
§ 134002(e)(1)(A)(i)	3
§ 134002(e)(1)(A)(iii)	3, 10
§ 134002(e)(1)(B).....	3, 18
§ 134002(e)(2)	18

United States Code

Title 15 § 2	3, 18
Title 35 § 261.....	13
Title 35 § 282(a)	14
Title 35 § 282(b)	14

CONSTITUTIONAL PROVISIONS

First Amendment	12
Eighth Amendment.....	16, 18

OTHER AUTHORITIES

Murat C. Mungan, <i>Reverse Payments, Perverse Incentives</i> , 27 Harv. J. Law & Tech. 1 (2013).....	16
<i>Overview of Agreements Filed in FY 2016</i> , A Report by the FTC Bureau of Competition, https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/mma_report_fy2016.pdf	15
Robin C. Feldman, et al., <i>The Fatal Attraction of Pay-for-Delay</i> , 18 Chi.-Kent J. Intell. Prop. 249 (2019).....	2

INTRODUCTION

1
2 In the face of skyrocketing prescription drug prices, the California Legislature enacted
3 Assembly Bill (AB) 824 to help prevent anticompetitive sales in California that result from “pay-
4 for-delay” settlements by the pharmaceutical industry. Pay-for-delay settlements are agreements
5 whereby brand-name drug manufacturers pay generic drug companies not to sell their competing
6 drugs. In other words, the rival companies agree to extend the monopoly of the brand-name drug
7 and then share the associated monopoly profits—at the expense of California patient-consumers
8 who are forced to pay artificially higher drug prices. To be clear, AB 824 does not prevent patent
9 settlements. Indeed, it permits settlements involving payments to rivals where they are shown to
10 be procompetitive or justified as fair consideration. Rather, under AB 824, settlements are
11 presumptively anticompetitive only where the brand-name pays its rival to delay market entry of
12 its competing drug. Even then, drug companies have the opportunity to rebut this presumption.

13 AAM’s recycled motion should be denied for several reasons. As a threshold matter, AAM
14 lacks standing as it has failed to demonstrate that AB 824 causes the requisite injury in fact to
15 AAM’s members or that any alleged injury is fairly traceable to AB 824. AAM’s motion must be
16 denied for several additional reasons that this Court previously recognized.

17 *First*, AAM fails to demonstrate that it is likely to succeed on the merits of any of its
18 repackaged claims. AAM’s as-applied dormant Commerce Clause claim is unripe and lacks
19 merit. AAM has not demonstrated that its members will engage in conduct that falls within the
20 law’s scope, that the Attorney General would have any reason to enforce AB 824 against them, or
21 that the law has been applied in a way that gives rise to any genuine threat of imminent
22 enforcement. Even if AAM’s claim were ripe, AB 824 does not violate the dormant Commerce
23 Clause’s extraterritoriality doctrine. AB 824 does not resemble the rare law struck down under
24 this doctrine because it does not control conduct “wholly outside” of California. Far from it, the
25 law applies a presumption of anticompetitive illegality to pay-for-delay agreements and does not
26 extend the scope of California’s longstanding antitrust laws. In fact, like California’s pre-existing
27 antitrust laws, AB 824 targets only agreements to engage in anticompetitive sales *in California*.

28

1 Courts have routinely rejected extraterritorial challenges to state laws, like this one, that regulate
2 in-state sales and are indifferent to sales in other States.

3 AAM's remaining legal claims likewise fail. AAM fails to demonstrate that AB 824 is
4 preempted by any federal law. AAM's Excessive Fines Clause claim is unripe, and AAM cannot
5 demonstrate that the penalty is grossly disproportionate to the gravity of a defendant's offense.
6 AAM's due process arguments also fail because AB 824 provides companies with meaningful
7 opportunities to disprove the presumption of anticompetitive conduct that AB 824 establishes.

8 *Second*, AAM has not shown imminent, irreparable injury in the absence of a preliminary
9 injunction. To the contrary, enjoining AB 824 would harm the public. As the evidence
10 demonstrates, California patients are harmed when companies enter into anticompetitive pay-for-
11 delay agreements. Ensuring competition helps patients and employers access affordable drugs.

12 **FACTUAL BACKGROUND**

13 Rising drug costs have become an epidemic of great concern to all Californians and a
14 significant driver in the high cost of healthcare. Between 2011 and 2015, the price of prescription
15 drugs rose 62%, outpacing the rate of increase for all other health services. Request for Judicial
16 Notice (RJN) Ex. A at 5. These price increases deny California patients access to affordable
17 medicines. McPherson Decl. ¶ 8 (72% of adults did not fill a prescription primarily due to cost).

18 Anticompetitive pay-for-delay agreements between pharmaceutical companies significantly
19 contribute to these increasing drug prices. These agreements impede generic competition because
20 brand name drug companies pay rival companies *not* to bring their lower-cost generics to market.¹

21 In 2019, the California Legislature enacted AB 824 to assist California patients. Under AB
22 824, a settlement agreement between two pharmaceutical companies, where a brand-name
23 compensates a rival generic to delay California sales of its competing generic for a period of time,
24 is presumptively anticompetitive. Cal. Health & Saf. Code § 134002(a)(1).² AB 824 applies only
25

26 ¹ See RJN Ex. E at 8 (explaining pay-for-delay agreements are estimated to cost American
27 consumers \$3.5 billion per year); Robin C. Feldman, et al., *The Fatal Attraction of Pay-for-
28 Delay*, 18 Chi.-Kent J. Intell. Prop. 249, 256 (2019) (“a one-year delay in generic entry
represented a transfer of \$12 billion from consumers to producers”).

² Unless otherwise noted, all statutory references are to the California Health & Safety Code.

1 to “agreement[s] resolving or settling, on a final or interim basis, a patent infringement claim, *in*
2 *connection with the sale* of a pharmaceutical product” in California. *Id.* (emphasis added).

3 Such agreements “shall be presumed to have anticompetitive effects” only if two
4 prerequisites apply: (1) the generic “receives anything of value from another company asserting
5 patent infringement” and (2) the generic “agrees to limit or forego research, development,
6 manufacturing, marketing, or sales” for any period of time. § 134002(a)(1)(A)-(B). AB 824
7 explicitly states that “anything of value” does “not include a settlement of a patent infringement
8 claim in which consideration granted by the brand” consists of, among other things, compensation
9 “for saved reasonable future litigation expenses.” § 134002(a)(2)(C).

10 If this presumption arises, the company has an opportunity to rebut it by demonstrating that
11 (1) the value received by the company is “fair and reasonable compensation” or (2) the agreement
12 has directly generated procompetitive benefits and the procompetitive benefits of the agreement
13 outweigh the anticompetitive effects of the agreement. § 134002(a)(3)(A)-(B). Further, AB 824
14 does not preclude companies from asserting any other recognized antitrust defense.

15 AB 824 provides for only a civil penalty. § 134002(e)(1)(B). Such a penalty shall be either
16 (1) “an amount up to three times the value received by the party that is reasonably attributed to
17 the violation of this section,” or (2) “twenty million dollars (\$20,000,000), whichever is greater.”
18 § 134002(e)(1)(A)(i).³ “[R]easonably attributed to the violation” is “determined by California’s
19 share of the market for the brand drug at issue in the agreement.” § 134002(e)(1)(A)(iii).

20 After AB 824 was signed into law, AAM filed suit and sought a preliminary injunction,
21 which this Court denied. *AAM v. Becerra*, Mem. & Order on Pl.’s Mot. for Prelim. Inj., No. 2:19-
22 cv-02281, 2019 WL 7370421 (E.D. Cal. Dec. 31, 2019) (hereinafter “First PI Order”). This
23 Court subsequently denied AAM’s motion for an injunction pending appeal.

24 On appeal, the Ninth Circuit also denied AAM’s motion for an injunction pending appeal.
25 Following oral argument, the Ninth Circuit vacated this Court’s decision and ordered that AAM’s
26 complaint be dismissed because AAM had not shown that there was a “substantial risk” that AB

27 _____
28 ³ For comparison, under federal antitrust law, violators can be imprisoned up to ten years, and
companies can be fined up to \$100 million. 15 U.S.C. § 2.

1 824 would cause any of its members to suffer injury that is concrete, particularized, and
2 imminent. *AAM v. Becerra*, No. 20-15014, 2020 WL 4251776, at *1 (9th Cir. July 24, 2020).

3 **STANDARD OF REVIEW**

4 A preliminary injunction “may only be awarded upon a clear showing that” the plaintiff “is
5 likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of
6 preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the
7 public interest.” *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20, 22 (2008).

8 **ARGUMENT**

9 **I. AAM DOES NOT HAVE STANDING**

10 AAM has not met its burden of demonstrating Article III standing. *Lujan v. Defenders of*
11 *Wildlife*, 504 U.S. 555, 560 (1992); *Hunt v. Wash. Apple Advertising Comm’n*, 432 U.S. 333, 343
12 (1977) (for an association to have standing, the association’s members must have standing in their
13 own right). Article III requires that the plaintiff must have (1) suffered an “injury in fact,” (2)
14 that is “fairly traceable to the challenged conduct of the defendant,” and (3) that is “likely” to be
15 “redressed by a favorable judicial decision.” *Lujan*, 504 U.S. at 560-61. The “injury in fact”
16 must be “(a) concrete and particularized” and “(b) actual or imminent, not ‘conjectural’ or
17 ‘hypothetical.’” *Id.* at 560. AAM fails to demonstrate injury-in-fact and traceability.

18 AAM asserts that its members are presently suffering economic harm by continuing to
19 litigate rather than settle certain patent-infringement suits, costing them legal fees and lost
20 settlement opportunities. Mot. at 1-2.⁴ Putting aside evidentiary issues with AAM’s
21 declarations,⁵ it is not clear whether the potential settlements that AAM describes in its
22 declarations even come within the ambit of AB 824. One declaration makes no mention of an
23 agreement to forego anything covered by § 134002(a)(1)(B), such as sales or research. *See* Pl.’s
24 Ex. C. Other declarations use generic descriptors such as “MFN” (Pl.’s Exs. B ¶ 7, C ¶ 6) and
25 “industry-standard accelerator provision” (Pl.’s Ex. F ¶ 5) to describe key settlement provisions.

26 _____
27 ⁴ AAM asserts that AB 824 “has caused AAM members to accept less favorable settlement
28 terms” (Mot. at 1), but none of the declarations support this assertion. Indeed, AAM cites none.

⁵ Defendant submits with this Opposition a set of evidentiary objections to AAM’s declarations.

1 We simply cannot assume exactly what AAM means to encompass with such broad terminology.
2 Finally, the terms that some of the declarants describe may be subject to exceptions to AB 824.
3 See Pl.’s Ex. D ¶ 4 (describing “consideration reflecting . . . avoided litigation costs”); Pl.’s Ex. C
4 ¶ 6 (describing terms as “pro-competitive”). Far more detail is needed to assess AAM’s claims.

5 AAM’s members “cannot manufacture standing merely by inflicting harm on themselves
6 based on their fears of hypothetical future harm that is not certainly impending.” *Clapper v.*
7 *Amnesty Int’l USA*, 568 U.S. 398, 416 (2013). In *Clapper*, plaintiffs similarly argued that they
8 could establish standing based on the “costly and burdensome measures [they took] to protect the
9 confidentiality of their communications.” *Id.* at 415. In rejecting the alleged present injuries, the
10 Court explained that “allowing [plaintiffs] to bring this action based on costs they incurred in
11 response to a speculative threat would be tantamount to accepting a repackaged version of
12 [plaintiffs’] first failed theory of standing,” i.e. the likelihood that the federal government would
13 utilize the challenged law to intercept plaintiffs’ communications with foreign contacts in the
14 future. *Id.* at 416. Like *Clapper*, because any fear that AAM members have of the Attorney
15 General’s enforcement of AB 824 against them is highly speculative, business decisions AAM
16 members make while guided by such fears similarly cannot form the legal basis for standing. *See*
17 *also San Diego Cnty. Gun Rights v. Reno*, 98 F.3d 1121, 1129 (9th Cir. 1996) (“Plaintiffs’
18 ‘allegations of a subjective ‘chill’ are not an adequate substitute for a claim of specific present
19 objective harm or a threat of specific future harm.’”).⁶ Further, courts are understandably
20 “reluctan[t] to endorse standing theories that rest on speculation about the decisions of
21 independent actors.” *Clapper*, 568 U.S. at 414. Here, AAM alleges injury resulting from the
22 altered course of patent settlement negotiations. Mot. at 1. But AAM cannot unilaterally—

23
24 _____
25 ⁶ AAM cites *Bland v. Fessler*, 88 F.3d 729, 737 (9th Cir. 1996) for the proposition that foregone
26 revenue caused by compliance “under the cloud of the civil statute’s penalties” creates a live
27 controversy sufficient for Article III. Mot. at 8. *Bland*, however, is factually distinct. There,
28 plaintiff had engaged in the conduct proscribed by statute, and had stopped engaging in that
conduct due to a “threat” of enforcement. *Id.* at 737. In contrast, here, *no* declarant has stated
that they entered into an unlawful pay-for-delay agreement, even before AB 824 enactment. Nor
is there any evidence of a “threat” of enforcement.

1 through its speculative declarations—erase the pivotal and independent role that *opposing* parties
2 in patent litigation play in negotiating and ultimately reaching settlements.⁷

3 Additionally, AAM fails to demonstrate “a very significant possibility of future harm,”
4 despite the fact that it is seeking an injunction. *San Diego Cnty. Gun Rights*, 98 F.3d at 1126
5 (where “plaintiffs seek declaratory and injunctive relief only, there is a further requirement that
6 they show a very significant possibility of future harm; it is insufficient for them to demonstrate
7 only a past injury”). Underlying AAM’s theory of injury is the idea—rejected by the Ninth
8 Circuit—that AAM members fear AB 824’s “massive monetary penalties” (Pl.’s Exs. C ¶ 7, F ¶
9 6) that may or may not one day be imposed. Far from “certainly impending,” any theory of future
10 potential harm requires significant speculation about how the Attorney General will enforce AB
11 824. *Clapper*, 568 U.S. at 401. Such a theory of “*possible* future injury” does not satisfy Article
12 III standing. *Id.* at 409; *AAM*, 2020 WL 4251776, at *2.

13 AAM also fails to establish that any injury it alleges is “fairly traceable” to AB 824.
14 *Clapper*, 568 U.S. at 409. First, the alleged present economic harm that AAM members have
15 inflicted on themselves is a product of fear of enforcement. *Id.* at 417 (“the costs that [plaintiffs]
16 have incurred to avoid surveillance are simply the product of their fear of surveillance,” and are
17 thus not fully traceable to the challenged the law). Second, federal and state antitrust laws
18 *already* prohibited the types of settlements that AB 824 presumes to be anticompetitive. *Id.*
19 (Plaintiffs’ injuries “are not fully traceable” to the challenged law where “even before [the law]
20 was enacted, [plaintiffs] had a similar incentive to engage in many of the countermeasures that
21 they are now taking”). Third, AAM can likewise only speculate as to whether any hypothetical
22 future enforcement action would be under AB 824 or another antitrust enforcement mechanism,
23 including the Cartwright Act, the Unfair Competition Act or the Sherman Act. Such
24 “speculation” about whether enforcement would be under the challenged law “or some other
25 authority” shows that AAM “cannot satisfy the requirement that any injury in fact must be fairly
26

27 ⁷ See, e.g., Pl.’s Ex. D ¶¶ 3-4 (company “currently litigating a patent-infringement case that I
28 expect would have settled if AB 824 was not in effect”); Pl.’s Ex. F ¶ 6 (“[A] procompetitive
settlement could otherwise—i.e., in the absence of AB 824—have been reached.”).

1 traceable to” the challenged law. *Clapper*, 568 U.S. at 410-11. Finally, to the extent AAM
 2 alleges that opposing parties in patent litigation have changed their settlement behavior as a result
 3 of AB 824, such assertions are insufficient to establish traceability to AB 824. *Id.* at 417 n.7 (to
 4 the extent plaintiffs “assert that third parties might be disinclined to speak with them due to fear
 5 of surveillance” under the challenged law, “they do not establish injury that is fairly traceable”).⁸

6 **II. AAM IS NOT LIKELY TO SUCCEED ON THE MERITS**

7 **A. AB 824 Does Not Violate the Commerce Clause**

8 AAM’s primary challenge to AB 824—that AB 824 violates the dormant Commerce Clause
 9 because it applies “wholly” outside of California—is unripe and lacks merit.⁹

10 **1. AAM’s Pre-Enforcement, As-Applied Dormant Commerce Clause 11 Claim Is Not Constitutionally Ripe**

12 To bring a pre-enforcement, as-applied challenge, a plaintiff must demonstrate “(1) a
 13 concrete plan to violate the law; (2) a communicated threat of prosecution; and (3) a history of
 14 past prosecution or enforcement of the challenged law.” First PI Order 10 (citing *Clark v. City of*
 15 *Seattle*, 899 F.3d 802 (9th Cir. 2018); *Maldonado v. Morales*, 556 F.3d 1037, 1044 (9th Cir
 16 2009)). AAM has again “made no attempt to establish these three constitutional elements.” *Id.*¹⁰

17 AAM restates that its members have chosen not to settle or to settle on purportedly less
 18 favorable terms due to their fears or interpretations of AB 824. Mot. at 1-2. Again, AAM has not

19 _____
 20 ⁸ See, e.g., Pl.’s Ex. B ¶ 9 (“Because of AB 824, however, [the opposing party] withdrew the offer
 21 of an MFN clause.”; Pl.’s Ex. F ¶ 5 (“In light of AB 824 and conversations the plaintiff
 22 apparently had with the State, the plaintiff informed [declarant company] that it could not agree to
 23 the terms it had previously offered.”).

24 ⁹ AAM mentions in a footnote that “[o]n its face, AB 824 applies to settlement agreements
 25 completed outside of California.” Mot. at 7 n.1. If AAM were asserting a “facial challenge under
 26 the dormant Commerce Clause, [AAM] must establish ‘that *no set of circumstances* exists under
 27 which the [AB 824] would be valid.’” *Rosenblatt v. City of Santa Monica*, 940 F.3d 439, 444
 28 (9th Cir. 2019) (emphasis added). “[I]nvalidating or even preliminarily enjoining the law on this
 basis would force the Court to not only assume the Attorney General will apply the law
 unconstitutionally, but also to make a constitutional determination before it is necessary to do so.”
 First PI Order 8.

¹⁰ AAM indicates that this three-factor test applied in *Thomas* (*infra* at 7) “does not control
 when—as here—plaintiffs allege ‘tangible economic injury’ due to the challenged law arising
 from forbearance of economic activity.” Mot. at 8 n.2 (citing *Nat’l Audubon Soc’y, Inc. v. Davis*,
 307 F.3d 835, 855 (9th Cir. 2002)). But *Davis* was not a pre-enforcement challenge, as a trapper
 had “been arrested and prosecuted” for violating the challenged law. *Id.* at 843 & n.4.

1 shown that any member has a concrete plan to violate the law or has executed any agreement that
2 would come within the ambit of AB 824. Importantly, AAM’s declarations fail to describe any
3 conduct occurring in California, in that the declarants do not indicate whether California sales
4 would be included in the alleged potential settlements—which is necessary to make AB 824
5 applicable. *See infra* at 9-11; *Compare NIFLA v. Harris*, 839 F.3d 823, 833 (9th Cir. 2016), *rev’d*
6 *on other grounds*, 138 S. Ct. 2361 (2018) (plaintiffs stated they would not comply with the law);
7 *Oklevueha Native American Church of Hawaii v. Holder*, 676 F.3d 829, 836 (9th Cir. 2012)
8 (plaintiff admitted to violating law “daily”).

9 AAM asserts that there is a communicated threat of prosecution because during the Ninth
10 Circuit oral argument, counsel for the Attorney General explained the contours of AB 824. Mot.
11 at 7. Once again, AAM misconstrues statements made. Such statements were made about the
12 *merits* of AAM’s dormant Commerce Clause challenge and explained the scope of AB 824. Pl.’s
13 Ex. A at 22:24-25; 23:1-3. Those statements do not constitute a “threat of prosecution” for
14 purposes of ripeness. *Compare Oklevueha*, 676 F.3d at 834 (government seized marijuana
15 pursuant to challenged statute); *NIFLA*, 839 F.3d at 833 n.4 (enforcement letter sent from state to
16 plaintiff); *Maldonado*, 556 F.3d at 1044-45 (statute enforced against plaintiff).

17 Finally, AAM makes *no* attempt to show past prosecution or enforcement of the law. *See*
18 *Thomas v. Anchorage Equal Rights Com’n*, 220 F.3d 1134, 1140-41 (9th Cir. 2000) (en banc)
19 (case not ripe where no complaint filed with the state, no investigation initiated by the state, and
20 no evidence of “active enforcement” of the challenged statute); *compare Susan B. Anthony List v.*
21 *Driehaus*, 573 U.S. 149, 164-165 (2014) (challenged statute already enforced against plaintiff,
22 state handles 20-80 cases/year under the statute, and “any person” can initiate an action).

23 2. AAM’s Dormant Commerce Clause Claim Is Not Prudentially Ripe

24 Separately, AAM’s pre-enforcement, as-applied claim is not prudentially ripe because the
25 dormant Commerce Clause claim is “not a purely legal issue and . . . additional facts are
26 necessary to address the Commerce Clause question.” First PI Order 11; *San Diego Cnty. Gun*
27 *Rights*, 98 F.3d at 1132 (“a concrete factual situation is necessary to delineate the boundaries of
28 what conduct the government may or may not regulate without running afoul of the Commerce

1 Clause”). Prudential ripeness requires the court to consider: (1) fitness of the issues for judicial
2 decision and (2) hardship to the parties if the court were to withhold jurisdiction. *Thomas*, 220
3 F.3d at 1141; *Oklevueha*, 676 F.3d at 837 (“[C]ourts have regularly declined on prudential
4 grounds to review challenges to recently promulgated laws in favor of awaiting actual
5 application.”); *NIFLA*, 839 F.3d at 833 (“Litigant must show that withholding review would
6 result in direct and immediate hardship, entailing more than possible financial loss”).

7 This Court need not speculate about “hypothetical” or “imaginary” cases as to how AB 824
8 may or may not one day be applied by the Attorney General in his discretion. *Thomas*, 220 F.3d
9 at 1139; *Golden v. Zwickler*, 394 U.S. 103, 108 (1969) (“federal courts established pursuant to
10 Article III of the Constitution do not render advisory opinions”). Indeed, injunctive relief is
11 available *on appropriate factual records* in as-applied challenges under the dormant Commerce
12 Clause. *See, e.g., Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608, 612-13 (9th Cir. 2018)
13 (affirming as-applied preliminary injunction based on actual application of statute).

14 **3. AAM’s Dormant Commerce Clause Fails on the Merits**

15 AAM has also not demonstrated a likelihood of success on the merits of its dormant
16 Commerce Clause claim. AAM’s claim rests on an extraterritoriality theory. Under this theory,
17 AAM must demonstrate that AB 824—an evidentiary, burden-shifting statute—is regulating
18 conduct “wholly outside the boundaries of a State.” *Healy v. Beer Inst.*, 491 U.S. 324, 336
19 (1989). “In the modern era, the Supreme Court has rarely held that statutes violate the
20 extraterritoriality doctrine.” *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1101 (9th
21 Cir. 2013). And this case is no exception.

22 1. AB 824 does not change the scope of existing state antitrust law. Where there is an
23 agreement or conspiracy to engage in anti-competitive conduct in a particular state, that state can
24 apply its antitrust law to redress or punish that agreement. *See, e.g., Knevelbaard Dairies v. Kraft*
25 *Foods, Inc.*, 232 F.3d 979, 985, 994 (9th Cir. 2000) (describing application of Cartwright Act to
26 out-of-state companies’ price-fixing conspiracy that effectively determined California milk
27 prices); *In re Cipro Cases I & II*, 348 P.3d 845, 852-53 (Cal. 2015) (describing “wave of state . . .
28 antitrust suits,” including under the Cartwright Act, filed in response to an anti-competitive

1 settlement agreement to delay generic market entry).¹¹ AB 824 reaches no further. In fact, it
2 simply alters the presumption and penalties applicable to conduct that was already illegal under
3 California law. Put simply, AAM's challenge is not to the scope of AB 824 but, rather, to the
4 well-settled scope of state antitrust law. And, because AB 824 does not alter that scope, any
5 questions AAM may want to raise about that scope cannot be answered here. Moreover, AAM's
6 challenge strains credulity: that the decades of application of state antitrust law to
7 anticompetitive agreements concerning sales in the regulating states is suddenly an affront to
8 horizontal federalism or that conspiring manufacturers can evade California's antitrust laws
9 simply by entering into their anti-competitive agreement in another state.

10 2. As the plain language of the statute makes clear, AB 824 seeks to prevent or reduce
11 anticompetitive pharmaceutical sales in California and, thus, applies to agreements to engage in
12 that conduct. *See* § 134002(a)(1) (describing "agreement[s], resolving or settling . . . patent
13 infringement claim[s], in connection with the sale of a pharmaceutical product" in California);
14 § 134000(c) (defining "agreement" as only that which "would constitute an agreement under
15 California state law or a 'trust' under the Cartwright Act"); § 134002(e)(1)(A)(iii) (penalty
16 determined by "California's share of the market").¹² AB 824 does not, therefore, regulate

17 ¹¹ *See also, e.g., Brand Name Prescription Drugs*, 123 F.3d 599, 613 (7th Cir. 1997) (applying
18 Alabama antitrust law in action by Alabama retail pharmacies against out-of-state drug
19 manufacturers for engaging in anti-competitive practices in their dealings with wholesalers that,
20 in turn, sold to retail pharmacies in Alabama); *In re Lorazepam*, 295 F. Supp. 3d 30, 48 (D.D.C.
21 2003) (Illinois Antitrust Act extends not only to illegal activity that occurred wholly in Illinois but
22 also to conduct that occurred, in part, outside of Illinois); *RLH Indus.*, 35 Cal. Rptr. 3d at 479
23 (applying Cartwright Act to out-of-state company's allegedly anti-competitive business practice
24 and concluding "that the commerce clause, even as construed in *Healy*, does not necessarily
25 prohibit state antitrust . . . law from reaching out-of-state anticompetitive practices injuring state
26 residents."); *Younger v. Jensen*, 605 P.2d 813, 816-19 (Cal. 1980) (describing California state-law
27 antitrust investigation of anti-competitive practices by Alaskan natural-gas producers whose gas
28 was sold in "transactions that have interstate aspects but significantly affect state interests");
Olstad v. Microsoft Corp., 700 N.W.2d 139, 142 (Wisc. 2005) (application of Wisconsin antitrust
law to out-of-state company's allegedly anti-competitive business practice); *Heath Consultants,
Inc. v. Precision Instruments, Inc.*, 527 N.W.2d 596, 606 (Neb. 1995) (similar); *State v. Sterling
Theatres Co.*, 394 P.2d 226, 227 (Wash. 1964) (similar).

¹² Even if there were any reason to think AB 824 applies to agreements not to compete in markets
other than California's, canons of construction compel the Court to construe AB 824 in a
constitutional manner. *Rosenblatt*, 940 F.3d at 444, 447; *IMS Health Inc. v. Mills*, 616 F.3d 7, 25
(1st Cir. 2010) (applying rules of statutory construction, Maine statute does not violate
extraterritoriality branch of the dormant Commerce Clause); *RLH Indus., Inc. v. SBC Commc'ns*,

1 conduct occurring wholly outside California. In fact, if manufacturers want to avoid application
2 of AB 824 to agreements they enter into, they can do so simply by omitting California sales from
3 those covered by the agreement. In this sense, AB 824 is no different from a host of other state
4 laws that courts have upheld because the laws were “indifferent” to sales in other States. *Nat’l*
5 *Elec. Mfrs. Ass’n v. Sorrell*, 272 F.3d 104, 110 (2d Cir. 2001) (quoting *Cotto Waxo Co. v.*
6 *Williams*, 46 F.3d 790, 794 (8th Cir. 1995)); *see also Rocky Mountain Farmers Union*, 730 F.3d
7 at 1102 (upholding California fuels regulation that said “nothing at all about ethanol produced,
8 sold, and used outside California”).

9 The fact that the decision—or agreement—to engage in unlawful sales in California may be
10 made outside the state does not put those decisions out of the state’s reach. Indeed, in many cases
11 where courts have rejected extraterritorial regulation, the relevant decisions—about product
12 labeling, product content, or production methods—are made out of state. *E.g.*, *Sorrell*, 272 F.3d
13 at 110. Similarly, the Ninth Circuit recently rejected an extraterritorial challenge to Arizona’s
14 regulation of horseracing “simulcasts originating from out-of-state racetracks” because the state
15 law “merely set[] the terms of doing business [for companies] choos[ing] to provide simulcasts in
16 the state.” *Monarch Content Mgmt. LLC v. Ariz. Dep’t of Gaming*, 971 F.3d 1021, 1031 (9th Cir.
17 2020). AB 824 does no more: it sets the terms of doing business in California (and no other
18 state).

19 Notably, state antitrust law, which AB 824 simply enhances with a shift in presumption and
20 an increase in penalties, governs the prices for which goods are sold *in California* by prohibiting
21 anticompetitive pricing agreements that increase prices for California consumers. When the
22 Supreme Court has struck down price controls as extraterritorial regulations, it has done so
23 because those laws controlled prices in *other States*. *Healy*, 491 U.S. at 338 (striking down
24

25 _____
26 *Inc.*, 35 Cal. Rptr. 3d 469, 480 (2005) (“California law embodies a presumption against the
27 extraterritorial application of its statutes”); *see, e.g., Chinatown Neighborhood Ass’n v. Harris*,
28 794 F.3d 1136, 1139 (9th Cir. 2015) (California law that makes it unlawful for “any person to
possess, sell, offer for sale, trade or distribute a shark fin” in California does not violate
extraterritoriality doctrine).

1 Connecticut law that had “the practical effect of controlling Massachusetts prices”).¹³ By
 2 contrast, the Supreme Court rejected an extraterritorial regulation challenge where the state law
 3 did not “regulate the price of any out-of-state transaction, either by its express terms or by its
 4 inevitable effect.” *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 669 (2003).

5 3. Recent Ninth Circuit caselaw does not support AAM. *Cf.* Mot. at 9. For instance,
 6 *Sam Francis Found. v. Christies, Inc.* upheld the portion of the law applicable to in-state sales,
 7 striking down only the portion that applied to other, out-of-state sales. 784 F.3d 1320, 1322 (9th
 8 Cir. 2015) (en banc). AB 824 does not apply to out-of-state sales. *Daniels Sharpsmart* is even
 9 farther afield because it did not even concern the State’s power to regulate sales; instead, in that
 10 case, the Court struck down specific application of California’s Medical Waste Management Act
 11 to waste disposal occurring entirely outside of California. 889 F.3d at 612-13.¹⁴

12 4. AAM has not presented evidence that “conflicting, legitimate legislation is already in
 13 place or that the threat of such legislation is actual and imminent,” as is required to bring a
 14 dormant Commerce Clause challenge. *Rocky Mountain Farmers Union*, 730 F.3d at 1104-05;
 15 *Ass’n des Eleveurs de Canards et d’Oies du Quebec v. Harris*, 729 F.3d 937, 951 (9th Cir. 2013)
 16 (“[T]he [Supreme] Court has never invalidated a state or local law under the dormant Commerce
 17 Clause based upon mere speculation about the possibility of conflicting legislation.”).¹⁵

18 _____
 19 ¹³ Plaintiff’s lead case, *Baldwin v. G.A.F. Seelig*, 294 U.S. 511 (1935), held that the challenged
 20 law was protectionist—that it discriminated against out-of-state firms to advantage in-state
 21 competitors. *Id.* 522 (rejecting argument that New York “may guard” its producers “against
 22 competition with the cheaper prices of Vermont”). To the extent *Baldwin* may be viewed as
 23 articulating extraterritorial regulation principles, it does not add to *Healy*’s prohibition against one
 24 State controlling prices in another. *Id.* at 521. Plaintiffs allege neither protectionism nor control
 25 of out-of-state prices here.

26 ¹⁴ See also *Ass’n for Accessible Meds. v. Frosh*, 887 F.3d 664, 667, 671 (4th Cir. 2018) (striking
 27 down Maryland statute because it applies to conduct occurring wholly outside state boundaries).

28 ¹⁵ AAM’s “pre-enforcement as-applied challenge is also problematic because it may be construed
 as an attempt to extend a facial overbreadth challenge outside the First Amendment context.”
 First PI Order 11 n.3. “The Supreme Court has regularly declined to extend such an analysis to
 other constitutional challenges.” *Id.*; see also *Sabri v. United States*, 541 U.S. 600, 609-10 (2004)
 (explaining Supreme Court has recognized overbreadth challenges in “relatively few settings”
 which derive from substantive First Amendment law). “Plaintiff claims that the language of [AB
 824] is overbroad because it may allow the government to enforce it unconstitutionally.” First PI
 Order 11 n.3. “[U]nder Plaintiff’s logic, any [California] law regarding commerce . . . would
 have to include language specifically limiting its application to within California. That simply
 cannot be the case” *Id.*

1 **B. AB 824 Is Not Preempted**

2 AAM asserts conflict preemption, under which state laws are preempted when they conflict
3 with federal law, including where “compliance with both federal and state regulations is a
4 physical impossibility” and where the challenged state law “stands as an obstacle to the
5 accomplishment and execution of the full purposes and objectives of Congress.” *Chinatown*
6 *Neighborhood Ass’n*, 794 F.3d at 1141. There is a presumption against preemption that generally
7 applies, and is particularly strong, where as here, federal law operates in a field which states
8 traditionally occupy. *Id.* Both antitrust and healthcare are areas traditionally regulated by States.
9 *California v. ARC Am. Corp.*, 490 U.S. 93, 101 (1989) (describing as “plain” that antitrust is an
10 area traditionally regulated by states); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)
11 (acknowledging “the historic primacy of state regulation of matters of health and safety”).
12 AAM asserts that AB 824 conflicts with four different federal laws: (1) federal patent law; (2)
13 *FTC v. Actavis*, 570 U.S. 136 (2013); (3) the Hatch-Waxman Act; and (4) the Biologics Price
14 Competition and Innovation Act of 2009 (BPCIA).¹⁶ All four arguments fail.

15 **1. AB 824 Does Not Conflict with Patent Law**

16 First, AAM argues that AB 824 is preempted by patent law because it bars “exclusive
17 licenses.” Mot. at 10-11 (citing 35 U.S.C. § 261). But AB 824 does not reach exclusive licenses
18 unless the license is given to induce a rival to agree not to compete. This unbridled use of
19 exclusive licenses to delay competition is not given by or protected by patent law. *See King Drug*
20 *Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 407 (3d Cir. 2015) (“[E]ven
21 exclusive licenses cannot avoid antitrust scrutiny where they are used in anticompetitive ways.”);
22 Br. for United States as Amicus Curiae, *SmithKline v. King Drug*, 2016 WL 5765167, at *11-13
23 (Oct. 3, 2016) (rejection by federal antitrust authorities of similar arguments). Second, AAM

24 _____
25 ¹⁶ AAM asserts that “‘a finding of conflict preemption’ is particularly likely when the regulatory
26 environment demands a ‘balance between competing statutory objectives.’” Mot. 12 (quoting
27 *Farina v. Nokia Inc.*, 625 F.3d 97, 123 (3d Cir. 2010)). *Farina*, however, is distinguishable
28 because there the FCC *itself* explicitly stated (1) in its rulemaking notice that certain guidelines
“constituted a balancing of safety and efficiency” and (2) in an amicus brief “that state-law claims
would upset that balance.” 625 F.3d at 126-27. The court explained that where “the subject
matter is technical and the relevant history and background are complex and extensive,” courts
defer to “an agency’s explanation of how state law affects the regulatory scheme.” *Id.* at 126.

1 argues that AB 824 “erases the ordinary presumption of patent validity.” Mot. at 10. AB 824
 2 does not alter the presumption of validity; it prohibits factfinders from presuming that any patent
 3 is enforceable. *See* First PI Order 13 (“[b]ecause AB 824 does not require determination of the
 4 validity of a patent and does not create patent-like protections, it does not conflict with federal
 5 patent law and is therefore not preempted under this analysis”).¹⁷ The Patent Act, 35 U.S.C.
 6 § 282(a), does *not* state that a patent shall be presumed “enforceable,” but rather that the patent is
 7 presumed “valid,” a distinction with a difference. *See* 35 U.S.C. § 282(b) (using “enforceable” as
 8 distinct from “valid”). Generally, validity relates to whether the patent conforms with certain
 9 statutory requirements; whereas enforceability relates to whether the patent was procured by
 10 fraud or wrongdoing. *See, e.g., Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1310-15 (Fed.
 11 Cir. 2000) (reviewing evidence regarding validity, distinct from enforceability).¹⁸

12 2. AB 824 Is Not Preempted by *Actavis*

13 AAM argues that “under *Actavis*, antitrust review of patent settlements is permitted only if
 14 a settlement has a ‘large and unjustified’ payment from the patent holder to the patent
 15 challenger—and even then, only pursuant to the rule of reason.” Mot. at 14. First, as this Court
 16 recognized, “*Actavis* allows the enforcement of antitrust law on patent settlements.” First PI
 17 Order 15; 570 U.S. at 141, 149. The absence of patent law protection of pay-for-delay
 18 settlements did not turn on the size of the payments. Rather, *Actavis*’ reference to the “large and
 19 unjustified” payment was simply the Court’s means of assessing when an agreement *might* be
 20 considered anticompetitive under federal antitrust law. *Id.* at 158. The size of the payment does

21
 22 ¹⁷ AAM summarizes *Buckman Co. v. Plaintiffs’ Legal Committee* as holding that “federal patent
 23 law” impliedly pre-empted state-law fraud-on-the-FDA claims because allowing plaintiffs to
 24 bring such tort claims against “patent holders” would skew the delicate balance of statutory
 25 objectives “the federal patent laws establish.” Mot. at 11 (citing *Buckman*, 531 U.S. 341, 348
 26 (2001)). But *Buckman* was not about patent law, and “patent” is nowhere to be found in the
 27 opinion. *See Buckman*, 531 U.S. at 341-55. That case is also distinguishable from the case at
 28 hand because “in contrast to situations implicating ‘federalism concerns and the historic primacy
 of state regulation of matters of health and safety,’ no presumption against pre-emption” applied
 in *Buckman*. *Id.* at 348. That is because “[p]olicing fraud against federal agencies is hardly ‘a
 field which the States have traditionally occupied.’” *Id.* at 347.

¹⁸ Moreover, punishing anti-competitive pay-for-delay settlements in no way undermines the
 presumption of validity. *Actavis*, 570 U.S. at 157. *Actavis* made clear that no provision of the
 Patent Act protects pay-for-delay agreements from federal antitrust scrutiny.

1 not delineate the proper boundary of antitrust and patent law; it simply drives the application of
2 federal antitrust law to the settlement agreement. *See* First PI Order 15-16. Second, *Actavis*'
3 adoption of a "rule of reason" approach is directly tied to *federal* antitrust authority and does not
4 bind or limit state antitrust law which can be broader and more restrictive. *ARC Am. Corp.*, 490
5 U.S. at 105 (no "federal policy against States imposing liability in addition to that imposed by
6 federal law"); *Cipro*, 348 P.3d at 871-73; First PI Order 15 (*Actavis* does not "prevent
7 California's imposition of a law establishing a presumption").

8 **3. AB 824 Does Not Conflict with the Hatch-Waxman Act**

9 AB 824's restriction on pay-for-delay provisions in settlement agreements *serves* rather
10 than frustrates the goals of the Hatch-Waxman Act. *See* Br. for Rep. Henry A. Waxman, *FTC v.*
11 *Actavis*, 2013 WL 417736, at *21 (Jan. 29, 2013) (Hatch-Waxman Act meant to "encourage"
12 generics "to enter the market, *not* to authorize them to use their increased leverage to exact a
13 share of the brand-name drug owner's monopoly profits in return for *staying out of the market*").
14 Like the Hatch-Waxman Act, AB 824 seeks to place generic drugs in the hands of patients faster.

15 Ignoring the wholly harmonious nature of AB 824 with the Hatch-Waxman Act, AAM's
16 preemption argument rests on mischaracterizations of AB 824. According to AAM, AB 824 will
17 diminish patent settlements by making them costlier. *See* Mot. at 14. But AB 824 specifically
18 *allows* settlements as long as the settlements do not call for anticompetitive pay-for-delay
19 compensation. *See Actavis*, 570 U.S. at 158 ("parties may well find ways to settle patent disputes
20 without the use of reverse payments"); *Cipro*, 348 P.3d at 868-69 ("[p]arties can still use financial
21 considerations" to settle patent disputes; the settlements barred are those that "would simply have
22 facilitated the sharing of monopoly profits"). Clearly, brand drug companies do not need to pay
23 rival generic companies to settle patent suits they themselves brought against their rivals. This is
24 further made clear by the FTC's review of the face of 232 patent settlement agreements in which
25 only 30 contained explicit compensation from a brand manufacturer to its rival.¹⁹

26 _____
27 ¹⁹ *Overview of Agreements Filed in FY 2016*, A Report by the FTC Bureau of Competition,
28 https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement/mma_report_fy2016.pdf.

1 Similarly, AAM claims that AB 824 will “inhibit the flow of generic medicines onto the
2 market.” Mot. at 13. But, “standard economic theory suggests reducing unfettered access to
3 reverse patent settlements would chill generic challenges to strong, likely valid patents more than
4 challenges to weak patents. The effect would be to increase the value of strong patents, while still
5 leaving generics incentives to challenge weak patents.” *Cipro*, 348 P.3d at 868 (citing Murat C.
6 Mungan, *Reverse Payments, Perverse Incentives*, 27 Harv. J. Law & Tech. 1, 7 (2013)).

7 **4. AB 824 Does Not Conflict with the BPCIA**

8 AAM asserts that AB 824 is preempted by the BPCIA. Mot. at 14 (citing *Amgen Inc. v.*
9 *Sandoz Inc.*, 877 F.3d 1315, 1328-30 (Fed. Cir. 2017)). However, the *Amgen* case stands for the
10 unremarkable proposition that the BPCIA preempts state law remedies for a BPCIA applicant’s
11 failure to comply with the BPCIA notice provision. 877 F.3d at 1320. This is far from what
12 AAM represents is a blanket ruling that states cannot regulate drug sales within the state.

13 **C. AB 824 Does Not Violate the Prohibition on Excessive Fines**

14 AAM contends that AB 824 violates the Eighth Amendment’s Excessive Fines Clause.
15 Confusingly, AAM states that its claim is both (1) “as applied in the sense that it does not seek to
16 strike the [penalty] in all its applications, but only to the extent it applies to *persons* who received
17 no value” and (2) “facial in that it is not limited to [a] particular case, but challenges application
18 of the law more broadly.” Mot. at 16 (citing *Doe v. Reed*, 561 U.S. 186, 194 (2010)). However,
19 AAM’s “attack is necessarily an as-applied pre-enforcement attack” “[b]ecause [AAM] seeks to
20 invalidate or enjoin the penalty provision of AB 824 as it might be applied to [certain] individuals
21 only.” First PI Order 19; *Doe*, 561 U.S. at 194 (where a plaintiff’s claim and requested relief
22 “reach beyond” particular circumstances of a plaintiff, a plaintiff must satisfy the court’s
23 “standards for a facial challenge”).

24 Once again, AAM “fails to cite to any authority that an as-applied pre-enforcement claim is
25 cognizable under the Excessive Fines Clause.” *Id.* Even if cognizable, there are no facts to
26 assess whether AB’s 824’s penalty is grossly disproportionate.

27
28

1 **1. AAM’s Excessive Fines Claim Is Not Ripe**

2 AAM has not met the threshold requirements for ripeness to assert its pre-enforcement
3 Excessive Fines claim. AAM has “made no attempt to proffer evidence that a single individual
4 intends to violate AB 824, nor that the State has communicated a threat of levying a \$20 million
5 fine” against an individual. First PI Order 19. The prudential inquiry also points to a finding that
6 “the claim is unripe as it requires factual development.” *Id.*

7 To determine if a penalty is “grossly disproportionate” to the gravity of the violation, a
8 court considers: (1) the nature and extent of the violation, (2) whether the violation was related to
9 other illegal activities, (3) other penalties that may be imposed for the violation, and (4) the extent
10 of the harm caused. *U.S. v. \$132,245.00 in U.S. Currency*, 764 F.3d 1055, 1058 (9th Cir. 2014).
11 These factors “are all but impossible to assess in the abstract, highlighting the difficulty of a pre-
12 enforcement attack based on the Excessive Fines Clause.” First PI Order 18. Here, there are
13 simply *no* facts to examine because AB 824 has not been applied at all, let alone to an individual.

14 **2. AAM’s Excessive Fines Claim Fails**

15 Excessive Fines claims require a court to assess whether the penalty is “grossly
16 disproportional” considering the four preceding factors. *\$132,245.00*, 764 F.3d at 1058. Because
17 the analysis is fact-specific, “[e]ven narrowing the challenge to the statute as it applies to
18 individuals, the [C]ourt cannot analyze the circumstances surrounding a violation before any
19 violation occurs.” First PI Order 20. There is further no reason to suspect AB 824’s penalty will
20 be disproportionate when ultimately enforced. And, AB 824 does not reach agreements that
21 cause no harm to consumers. *See* § 134002. Although AAM emphasizes the lack of value
22 received by a hypothetical individual, the proportionality of a penalty is measured against the
23 gravity of the harm, not the amount pocketed by the violator. *\$132,245.00*, 764 F.3d at 1058.
24 Here, a single pay-for-delay agreement can cause millions, even billions, of dollars of harm. *See*
25 Jantz Decl. ¶¶ 11, 12. And while AAM characterizes AB 824’s penalty as “excessive,” this is
26 belied by comparison with well-accepted penalties for antitrust violations. *See* Cal. Bus. & Prof.
27 Code § 16750(a) (authorizing treble damages), *id.* at § 16752 (authorizing revocation of right to
28

1 do business in state), *id.* at § 16750 (authorizing disgorgement); 15 U.S.C. § 2 (authorizing
2 individual fines and imprisonment up to ten years and company fines up to \$100 million).

3 Moreover, AAM’s argument hinges on a flawed and incomplete reading of AB 824.
4 Although AB 824’s penalty provision uses the term “person,” (§ 134002(e)(1)(A)) the same
5 provision also states that penalties “shall be recovered” “against any *party to an agreement* that
6 violates this section.” § 134002(e)(1)(B) (emphasis added); *see also* § 134002(e)(2). The parties
7 to pay-for-delay agreements are pharmaceutical companies, not natural persons—and certainly
8 not secretaries who merely “assist” in the transaction. *Gonzalez v. CarMax Auto Superstores,*
9 *LLC*, 840 F.3d 644, 650 (9th Cir. 2016) (when interpreting California statute, statute’s plain
10 meaning “cannot be determined without reference to the context in which the words are used”).²⁰

11 In any event, the Court “should grant substantial deference to the broad authority that
12 legislatures necessarily possess in determining the types and limits of punishments for crimes.”
13 *Solem v. Helm*, 463 U.S. 277, 290 (1983); *Water-Pierce Oil Co. v. Tex.*, 212 U.S. 86, 111 (1909)
14 (The fixing of “penalties for unlawful acts is within the police power of the state”).²¹

15 **D. AB 824 Does Not Violate Due Process**

16 AAM asserts that AB 824 violates the Due Process Clause because it does not provide
17 defendants “with ‘an opportunity to present every available defense’” and the defense of
18 demonstrating pro-competitive effects “cannot be eliminated by presumption.” Mot. at 18. But
19 AAM has not shown “that AB 824’s express provision allowing a manufacturer to rebut the

20 _____
21 ²⁰ In the unlikely event that, contrary to the statute’s plain language, the Attorney General sought
22 a \$20 million penalty against an individual, there would be nothing to prevent that individual
23 from raising an Excessive Fines Clause claim. *See Nevada v. Hicks*, 533 U.S. 353, 366 (2001)
24 (“state courts of ‘general jurisdiction’ can adjudicate cases invoking federal statutes” and they are
25 “presumptively competent [] to adjudicate claims arising under the laws of the United States”).

26 ²¹ Post-*Timbs*, deference still applies to the state legislature. *Timbs* held there is no daylight
27 between the application of the 8th Amendment to the federal and state courts. *Timbs v. Indiana*,
28 139 S. Ct. 682, 687 (2019). The Supreme Court has already provided guidance, emphasizing that
“judgment about the appropriate punishment for an offense belongs in the first instance to the
legislature.” *United States v. Bajakajian*, 524 U.S. 321, 336 (1998) (cautioning that “any judicial
determination regarding the gravity of a particular criminal offense will be imprecise”); *see also*
State ex rel. French v. Overstock.com, Inc., 2019 WL 2714835, at *4 (Del. Super. Ct. June 28,
2019) (post-*Timbs*, the court still “accord[s] substantial deference to the judgment of the General
Assembly” which “ha[s] broad initial authority to determine . . . appropriate penalties”).

1 presumption by showing procompetitive effects is not meaningful.” First PI Order 21. And, “the
 2 parties remain free to invoke any other standard antitrust defense.” *Id.*; *see also Speiser v.*
 3 *Randall*, 357 U.S. 513, 523 (1958) (state may “regulate procedures under which its laws are
 4 carried out, including the burden of producing evidence and the burden of persuasion”).²²

5 AAM again takes issue with AB 824’s “presumption that the relevant product market
 6 includes only the branded drug product and its generic substitutes.” Mot. at 17. As this Court
 7 concluded, “AB 824 simply erects a presumption regarding the relevant market. It does not
 8 foreclose defendant from presenting evidence that the relevant market is broader than the one
 9 presumed.” *Id.* at 22-23 (“[t]he presumption raised by AB 824 is stronger, and the burden shift
 10 may be sharper, but both federal and state antitrust caselaw provides for a similar presumption
 11 and burden shift in the context of reverse payment settlement agreements”).

12 **III. AAM HAS NOT DEMONSTRATED IMMINENT AND IRREPARABLE HARM**

13 AAM’s claim that it will suffer irreparable harm is largely based on self-inflicted economic
 14 injury, i.e. members’ independent business decisions whether to settle. Mot. at 18. Evidence
 15 demonstrates, however, that since AB 824 went into effect, AAM members have settled more
 16 than 40 patent infringement cases. Jantz Decl. at ¶¶ 15-16, Ex. A. This is unsurprising given that
 17 AB 824 prohibits only anticompetitive pay-for-delay settlements, and as the FTC report confirms
 18 the vast majority of patent litigations settle without payments to rivals. *See supra* at 15 n.19.
 19 Further, there has not been a statistically significant decrease in the number of ANDAs submitted
 20 in 2020. Jantz Decl. at ¶¶ 13-14. Finally, AAM’s assertion that AB 824 subjects its members to
 21 a law “that violates their constitutional rights” (Mot. at 18) is without merit given that AAM has
 22 failed to demonstrate a likelihood of success on its constitutional claims.

23 _____
 24 ²² *See also Cipro*, 348 P.3d at 864, 870 (“this method of analysis, and of assessing
 25 anticompetitive harm, is not materially different from that applied in any other garden-variety
 26 antitrust case,” including assessing the lawfulness of agreements “as of the time they are made”);
 27 *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003) (“the
 28 reasonableness of agreements under the antitrust laws are to be judged at the time the agreements
 are entered into”); *Polk Bros., Inc. v. Forest City Enters., Inc.*, 776 F.2d 185, 189 (7th Cir. 1985)
 (“A court must ask whether an agreement promoted enterprise and productivity at the time it was
 adopted.”); *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc) (asking
 whether Java and Navigator were competitive threats “at the time Microsoft engaged in the
 anticompetitive conduct at issue”).

1 **IV. ENJOINING AB 824 WOULD NOT BE IN THE PUBLIC INTEREST**

2 The last two preliminary injunction factors under the *Winter* test—the balance of hardships
3 and the public interest—weigh in favor of denying AAM’s request for a preliminary injunction.
4 *Winter*, 555 U.S. at 20; *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014).

5 California has an interest in protecting patients by ensuring that pharmaceuticals are
6 affordable. AB 824 is designed to curb the high costs of prescription drugs that affect not only
7 healthcare patients, but also payors such as employers and the Medicare and Medicaid programs.
8 RJN Exs. B at 1, C, D; Cressman Decl. ¶¶ 3-9; MacEdon Decl. ¶¶ 3-10; Doe Decl. ¶ 4;
9 McPherson Decl. ¶ 8; Cooper Decl. ¶¶ 10-11; Moulds Decl. ¶¶ 6, 9; *Cipro*, 348 P.3d at 873.

10 Moreover, “any time a State is enjoined by a court from effectuating statutes enacted by
11 representatives of its people, it suffers a form of irreparable injury.” *Maryland v. King*, 567 U.S.
12 1301, 1301 (2012). As the California Legislature, the California Supreme Court, and the FTC
13 have found, these pay-for-delay settlement agreements stifle competition, ultimately harming
14 patients and costing Californians millions of dollars. *Supra* at 2-3; *Cipro*, 348 P.3d at 868
15 (“insufficient scrutiny of [reverse payment] settlements has the potential to hamper innovation”).
16 If AB 824 is enjoined, California will have one less tool at its disposal to combat collusive
17 agreements, and consequently, Californians will be denied affordable drugs and experience
18 increasing insurance premiums. *See also Winter*, 555 U.S. at 27 (deference owed to government
19 officials in reviewing the public interest prong); *Sierra Forest Legacy v. Sherman*, 646 F.3d 1161,
20 1185-86 (9th Cir. 2011) (deference to States’ judgments “concerning interests in health and
21 welfare” is appropriate when considering whether to grant an injunction).²³

22 **CONCLUSION**

23 AAM’s motion for a preliminary injunction should be denied.

24
25
26 ²³ If the Court grants AAM’s motion, any relief should be limited to redressing the specific
27 injuries of the parties before this Court. *See Gill v. Whitford*, 138 S. Ct. 1916, 1921, 1933-34
28 (2018). Similarly, should the Court decide to enjoin any portion of AB 824, the Court should
allow the remainder to remain effective as AB 824 has a severance clause. §§ 134002(d)(2),
134002 Sec. 2 (“The provisions of this act are severable”); *MD/DC/DE Broadcasters Ass’n v.*
FCC, 236 F.3d 13, 22 (D.C. Cir. 2001).

1 Dated: October 15, 2020

Respectfully Submitted,

2 XAVIER BECERRA
3 Attorney General of California
4 EMILIO VARANINI
5 KARLI EISENBERG
6 Supervising Deputy Attorneys General

7 /s/ Jacqueline Palma Malafa
8 JACQUELINE PALMA MALAFA
9 Deputy Attorney General
10 *Attorneys for Defendant Xavier Becerra, in*
11 *his official capacity as Attorney General of*
12 *the State of California*

13 SA2020303019
14 34497951.docx
15
16
17
18
19
20
21
22
23
24
25
26
27
28