

**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. 2:19-cv-02281-TLN-DB

NOTICE OF PRELIMINARY INJUNCTION APPEAL

Notice is hereby given that Plaintiff Association for Accessible Medicines hereby appeals, pursuant to Ninth Circuit Rule 3-3, to the United States Court of Appeals for the Ninth Circuit from this Court's denial of Plaintiff's Motion for Preliminary Injunction, entered on Tuesday, December 31, 2019. A copy of this Court's Memorandum and Order on Plaintiff's Motion for Preliminary Injunction is attached hereto as Exhibit A.

Respectfully submitted,

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January 2, 2020

CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of January, 2020, I electronically filed the foregoing Notice of Preliminary Injunction Appeal with the Clerk of the Court for the United States District Court for the Eastern District of California using the CM/ECF system.

/s/ Matthew Rowen

EXHIBIT A

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

ASSOCIATION FOR ACCESSIBLE
MEDICINES,

 Plaintiff,

 v.

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

 Defendant.

No. 2:19-cv-02281-TLN-DB

**MEMORANDUM AND ORDER ON
PLAINTIFF’S MOTION FOR
PRELIMINARY INJUNCTION**

This matter is before the Court on Plaintiff Association for Accessible Medicine’s (“Plaintiff” or “AAM”) Motion for Preliminary Injunction requesting the Court enjoin the implementation or enforcement of Assembly Bill 824 (“AB 824”). (ECF No. 10.) Defendant Attorney General Xavier Becerra (“Defendant” or the “State”) filed an opposition on December 10, 2019. (ECF No. 24.) Plaintiff filed a reply on December 17, 2019. (ECF No. 27.) The Court also considered Amicus Curiae briefs submitted by various interested parties (ECF Nos. 21, 25), and the Court heard oral argument on December 19, 2020 (*See* ECF No. 28, hearing minutes). After carefully considering all material presented to the Court and for the reasons set forth below, Plaintiff’s Motion is DENIED.

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1 **I. FACTUAL AND PROCEDURAL BACKGROUND¹**

2 AB 824 creates a presumption that “reverse payment” settlement agreements regarding
3 patent infringement claims between brand-name and generic pharmaceutical companies are anti-
4 competitive and unlawful.

5 Reverse payment settlements arise primarily — if not exclusively — in the context of
6 pharmaceutical drug regulations and suits brought under the statutory provisions of the Drug
7 Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-
8 Waxman Act. Under the Hatch-Waxman Act, once a brand-name company has submitted a new
9 prescription drug to the FDA and gained approval to market it, a manufacturer of a generic drug
10 with the same active ingredients that is biologically equivalent to the approved brand-name drug
11 can gain approval to market the generic through an abbreviated FDA process. The New Drug
12 Application (“NDA”) process is long, comprehensive, and expensive whereas the Abbreviated
13 New Drug Application (“ANDA”) process that a generic drug is subjected to is substantially less
14 expensive and requires far less testing.

15 In order to gain approval through the FDA, the generic company must file an ANDA. As
16 part of this application, the generic company must assure the FDA that its drug will not infringe
17 on any patents owned by the brand-name drug company. One way to do so is for the generic
18 company to certify that any listed, relevant patent is invalid or will not be infringed by the
19 manufacture, use, or sale of the generic drug. This is called a Paragraph IV certification.
20 Because filing under Paragraph IV indicates that there are current patents that the generic
21 company asserts are invalid or un infringed by its product, the Paragraph IV certification is *per se*
22 a patent infringement and thus the brand-name company can, and often does, bring suit against
23 the generic drug manufacturer.

24 Settlements of the resulting lawsuits sometimes include reverse payments in which the
25 plaintiff, the brand-name drug company, pays the defendant, the infringing generic drug

26 ¹ The following recitation of facts is derived from Plaintiff’s Complaint (ECF No. 1), as
27 well as the parties’ briefing on the Motion for Preliminary Injunction (ECF Nos. 10, 24, 27).
28 Additionally, the Court gathered general background information from *FTC v. Actavis, Inc.*, 570
U.S. 136 (2013).

1 company, a sum of money for the promise that the generic drug company will keep its drug off
2 the market for an agreed-upon length of time.

3 AB 824 targets these types of settlements. According to the State, AB 824 closes this
4 loophole in the Hatch-Waxman Act and ensures that a brand-name drug company cannot continue
5 to enforce an otherwise weak patent against generics through these reverse payment settlements.

6 AB 824 imposes a presumption that a settlement agreement involving a brand-name
7 company compensating the generic for keeping its drug off the market is anticompetitive under
8 California Antitrust Law. It also levies a civil penalty against any individual who assists in the
9 violation of the section of three times the value received by the individual due to the violation or
10 \$20 million, whichever is greater.

11 Plaintiff asserts the following causes of action, all in an attempt to invalidate AB 824: (1)
12 Declaratory/Injunctive Relief — Commerce Clause — Extraterritoriality; (2)
13 Declaratory/Injunctive Relief — Preemption; (3) Declaratory/Injunctive Relief — Excessive
14 Fines Clause; (4) Declaratory/Injunctive Relief — Due Process — Burden Shifting; (5) 42 U.S.C.
15 § 1983 and 42 U.S.C. § 1988. (ECF No. 1 at 30–51.) More specifically, Plaintiff alleges AB 824
16 violates the Dormant Commerce Clause by directly regulating out-of-state conduct; is preempted
17 by federal patent law and the delicate balance between the competing interests of patent
18 protections and anti-trust law struck by the Supreme Court in *FTC v. Actavis, Inc.*, 570 U.S. 136
19 (2013); violates the constitutional prohibition of excessive fines under the Eighth Amendment; and
20 violates due process in that it creates a burden shift with no meaningful opportunity for defendant
21 to rebut the presumption applied. Presently before the Court is Plaintiff’s Motion (ECF No. 10)
22 seeking a preliminary injunction prohibiting the enforcement of this law, which would otherwise
23 take effect January 1, 2020.

24 II. STANDARD

25 Injunctive relief is “an extraordinary remedy that may only be awarded upon a clear
26 showing that the plaintiff is entitled to such relief.” *Winter v. Natural Res. Def. Council, Inc.*, 555
27 U.S. 7, 22 (2008) (citing *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam)). “The
28 purpose of a preliminary injunction is merely to preserve the relative positions of the parties until

1 a trial on the merits can be held.” *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981); *see also*
2 *Costa Mesa City Emps. Ass’n v. City of Costa Mesa*, 209 Cal. App. 4th 298, 305 (2012) (“The
3 purpose of such an order is to preserve the status quo until a final determination following a
4 trial.”); *GoTo.com, Inc. v. Walt Disney, Co.*, 202 F.3d 1199, 1210 (9th Cir. 2000) (“The status quo
5 ante litem refers not simply to any situation before the filing of a lawsuit, but instead to the last
6 uncontested status which preceded the pending controversy.”).

7 “A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed
8 on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief,
9 [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest.”
10 *Winter*, 555 U.S. at 20. A plaintiff must “make a showing on all four prongs” of the *Winter* test
11 to obtain a preliminary injunction. *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135
12 (9th Cir. 2011). In evaluating a plaintiff’s motion for preliminary injunction, a district court may
13 weigh the plaintiff’s showings on the *Winter* elements using a sliding-scale approach. *Id.* A
14 stronger showing on the balance of the hardships may support issuing a preliminary injunction
15 even where the plaintiff shows that there are “serious questions on the merits . . . so long as the
16 plaintiff also shows that there is a likelihood of irreparable injury and that the injunction is in the
17 public interest.” *Id.* Simply put, a plaintiff must demonstrate, “that [if] serious questions going to
18 the merits were raised [then] the balance of hardships [must] tip[] sharply in the plaintiff’s favor,”
19 in order to succeed in a request for preliminary injunction. *Id.* at 1134–35 (emphasis added).

20 III. STANDING

21 Neither party has raised any issues with respect to standing. Nevertheless, “federal courts
22 are required *sua sponte* to examine jurisdictional issues such as standing.” *Chapman v. Pier 1*
23 *Imports (U.S.) Inc.*, 631 F.3d 939, 954 (9th Cir. 2011) (quoting *Bernhardt v. Cty. of L.A.*, 279
24 F.3d 862, 868 (9th Cir. 2002)). And “[t]he existence of Article III standing is not subject to
25 waiver.” *Chapman*, 631 F.3d at 954. To establish Article III standing, a plaintiff must have “(1)
26 suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant,
27 and (3) that is likely to be redressed by a favorable judicial decision.” *Spokeo, Inc. v. Robins*, 136
28 S. Ct. 1540, 1547 (2016).

1 “[A]n association has standing to bring suit on behalf of its members when: (a) its
2 members would otherwise have standing to sue in their own right; (b) the interests it seeks to
3 protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief
4 requested requires the participation of individual members in the lawsuit.” *Hunt v. Washington*
5 *State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). Further, “[w]hether an association has
6 standing to invoke the court's remedial powers on behalf of its members depends in substantial
7 measure on the nature of the relief sought. If in a proper case the association seeks a declaration,
8 injunction, or some other form of prospective relief, it can reasonably be supposed that the
9 remedy, if granted, will inure to the benefit of those members of the association actually injured.
10 Indeed, in all cases in which we have expressly recognized standing in associations to represent
11 their members, the relief sought has been of this kind.” *Id.* (citing *Warth v. Seldin*, 422 U.S. 490,
12 515 (1975)).

13 Here, Plaintiff is a nonprofit, voluntary association representing the leading manufacturers
14 and distributors of generic and biosimilar medicines, manufacturers and distributors of bulk active
15 pharmaceutical ingredients, and suppliers of other goods and services to the generic and
16 biosimilar pharmaceutical industry. (ECF No. 1 ¶ 12.) As clarified at oral argument, Plaintiff
17 asserts representational standing on behalf of its members, alleging that its members have many
18 ongoing cases involving patent infringement, and other members are currently developing
19 generics and/or contemplating filing ANDAs. (ECF No. 1 ¶¶ 14–15.) Plaintiff seeks injunctive
20 relief while claiming its members will be injured by the implementation of AB 824. (ECF No. 1
21 ¶ 16.) The Court finds Plaintiff has sufficiently alleged the elements of representational standing
22 to bring the instant motion for preliminary injunction.

23 **IV. REQUEST FOR JUDICIAL NOTICE**

24 At the outset, Defendant requests the Court take judicial notice of five documents
25 pursuant to Federal Rule of Evidence 201: (1) Assembly Committee on Health AB 824 Bill
26 Analysis (March 26, 2019), attached to Defendant’s Request for Judicial Notice (“RJN,” ECF No.
27 24-1) as Exhibit A; (2) Assembly Floor Analysis of AB 824 (September 4, 2019), attached to
28 RJN as Exhibit B; (3) Letters of Support for AB 824, attached to RJN as Exhibit C; (4) Table 8:

1 Total All Payers State Estimates by State of Residence (1991–2014) — Drugs and Other Non-
2 durable Products (Millions of Dollars), attached to RJN as Exhibit D; and (5) *Pay-for-Delay:*
3 *How Drug Company Pay-Offs Cost Consumers Billions*, FTC Staff Study (Jan. 2010), attached to
4 RJN as Exhibit E. The State contends judicial notice of Exhibits A, B, and C is appropriate
5 because they are documents that are part of the legislative history of AB 824. The State asserts
6 Exhibits D and E are appropriate for judicial notice because the documents were “administered by
7 or filed with an administrative agency that is not subject to reasonable dispute and is ‘capable of
8 accurate and ready determination by resort to sources whose accuracy cannot reasonably be
9 questioned.’” (ECF No. 24-1 at 2, *quoting* Fed. R. Evid. 201.) Plaintiff does not oppose the
10 State’s request, and the Court finds all five documents are appropriate for judicial notice.

11 Exhibits A, B, and C are part of the legislative history of AB 824, and courts routinely
12 take judicial notice of legislative history documents. *Anderson v. Holder*, 673 F.3d 1089, 1094
13 n.1 (9th Cir. 2012) (citing *Chaker v. Crogan*, 428 F.3d 1215, 1223 n. 8 (9th Cir.2005))
14 (“Legislative history is properly a subject of judicial notice.”); *Korematsu v. United States*, 584 F.
15 Supp. 1406, 1414 (N.D. Cal. 1984) (citing *Territory of Alaska v. American Can Co.*, 358 U.S.
16 224, 227 (1959)) (“[C]ourts frequently take judicial notice of legislative history, including
17 committee reports.”). Similarly, a court “may take judicial notice of ‘records and reports of
18 administrative bodies.’” *Anderson*, 673 F.3d at 1094 (citing *Mack v. South Bay Beer Distributors,*
19 *Inc.*, 798 F.2d 1279, 1282 (9th Cir.1986)). Exhibit D — a summary table from the Centers for
20 Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group,
21 available on CMS.gov; and Exhibit E — an “FTC Staff Study” available on ftc.gov, are such
22 reports.

23 Defendant’s unopposed Request for Judicial Notice (ECF No. 24) is therefore GRANTED
24 and the Court hereby judicially notices Exhibits A through E attached thereto.

25 **V. PRELIMINARY INJUNCTION ANALYSIS**

26 Plaintiff’s Complaint asserts five causes of action, the first four of which encompass the
27 present request for preliminary injunction. As explained below, and primarily due to the nature of
28 Plaintiff’s pre-enforcement attack on AB 824, the Court finds Plaintiff has failed to establish a

1 likelihood of success on the merits of its claims, nor has it raised serious questions going to those
2 merits. Moreover, the Court finds that absent a constitutional violation Plaintiff has failed to
3 establish an irreparable harm that is both likely and — at this time — imminent. And lastly, even
4 if the Court were to find serious questions going to the merits of Plaintiff’s claims, the question of
5 balance of harms and public interest are too speculative at this point for the Court to find that
6 either factor favors Plaintiff, sharply or otherwise.

7 A. *Likelihood of Success on the Merits*

8 In an attempt to enjoin enforcement of AB 824 before it takes effect on January 1, 2010,
9 Plaintiff asserts the bill: (1) violates the Dormant Commerce Clause; (2) is preempted; (3) violates
10 the Excessive Fines Clause of the Eighth Amendment; and (4) violates the Due Process Clause.
11 Plaintiff’s attack on AB 824 is in part both facial and as-applied. As discussed below, Plaintiff
12 has failed to establish a likelihood of success on the merits of any of these claims and as a result,
13 the Court finds a preliminary injunction is inappropriate at this time.

14 1. Dormant Commerce Clause

15 In its moving papers, Plaintiff indicates AB 824 — because it is not limited to settlement
16 agreements entered into in California or between California entities — directly regulates out of
17 state commerce and is therefore a *per se* violation of the Dormant Commerce Clause.
18 Interpreting this as a facial attack on AB 824, the State argues that because AB 824 can
19 conceivably be applied to settlement agreements contained within California, it has at least one
20 constitutional application and so Plaintiff’s facial attack fails.

21 Indeed, a facial challenge is “the most difficult challenge to mount successfully, since the
22 challenger must establish that no set of circumstances exists under which the Act would be valid.
23 The fact that [an] Act might operate unconstitutionally under some conceivable set of
24 circumstances is insufficient to render it wholly invalid, since we have not recognized an
25 ‘overbreadth’ doctrine outside the limited context of the First Amendment.” *United States v.*
26 *Salerno*, 481 U.S. 739, 745 (1987). Facial challenges are disfavored because they often require
27 the court to make constitutional determinations based on hypothetical situations. *Washington*
28 *State Grange v. Washington State Republican Party*, 552 U.S. 442, 449–51 (2008) (“Claims of

1 facial invalidity often rest on speculation. As a consequence, they raise the risk of premature
2 interpretation of statutes on the basis of factually barebones records.” (internal citation omitted)).
3 Here, Plaintiff poses the hypothetical situation of non-California entities entering into a settlement
4 agreement outside of California, and then asks the Court to assume that California would seek to
5 enforce AB 824 against these hypothetical parties. But invalidating or even preliminarily
6 enjoining the law on this basis would force the Court to not only assume the Attorney General
7 will apply the law unconstitutionally, but also to make a constitutional determination before it is
8 necessary to do so. *Washington State Grange v. Washington State Republican Party*, 552 U.S.
9 442, 449–51 (2008) (“Facial challenges also run contrary to the fundamental principle of judicial
10 restraint that courts should neither anticipate a question of constitutional law in advance of the
11 necessity of deciding it nor formulate a rule of constitutional law broader than is required by the
12 precise facts to which it is to be applied.” (internal quotes and citations omitted)). Such a facial
13 attack therefore fails where, as here, a set of circumstances exists under which AB 824 will be
14 valid.

15 Plaintiff seems to concede this point, clarifying its position in its reply brief and in oral
16 argument that it is not raising a facial attack against AB 824, but an as-applied attack. (ECF No.
17 27 at 7.) An as applied challenge looks at a specific plaintiff and set of circumstances and
18 determines if the law is constitutional as applied to that set of circumstances. *Wal-Mart Stores,*
19 *Inc. v. City of Turlock*, 483 F. Supp. 2d 987, 996–97 (E.D. Cal. 2006) (citing 16 C.J.S.
20 Constitutional Law § 187) (“When faced with a claim that application of a statute renders it
21 unconstitutional, a court must analyze the statute as applied to the particular case, i.e., how it
22 operates in practice against the particular litigant and under the facts of the instant case, not
23 hypothetical facts in other situations”). In other words, Plaintiff claims AB 824 “*as applied* to
24 settlement agreements that were not negotiated, completed, or entered in California,” violates the
25 Dormant Commerce Clause. (ECF No. 27 at 7.) Indeed, if the Attorney General were to enforce
26 the terms of AB 824 against two out of state parties that entered into a settlement agreement
27 outside of California, having nothing to do with California, such conduct would likely violate the
28 Dormant Commerce Clause. In this case, however, AB 824 has yet to take effect. As a result, the

1 Court cannot consider the law *as it has been applied* to a particular agreement or party. Rather,
2 Plaintiff raises a “paradigmatic as-applied challenge” to AB 824, urging the Court to find that
3 “the application of the statute to a specific factual circumstance” is in violation of the Dormant
4 Commerce Clause. (*Id.* (citing *Hoye v. City of Oakland*, 653 F.3d 835, 857 (9th Cir. 2011)).)
5 Plaintiff asserts the fact that AB 824 hasn’t been enforced yet is not detrimental to its challenge,
6 citing case law in support of its position that a pre-enforcement as-applied challenge is ripe “so
7 long as [it] present[s] a ‘discrete and well-defined’ application of the challenged law that is ‘likely
8 to occur.’” (*Id.* (citing *Gonzales v. Carhart*, 550 U.S. 124, 167 (2007)).)

9 In oral argument, the State did not blanketly refute Plaintiff’s attempt to raise a pre-
10 enforcement as-applied attack on AB 824, but rather highlighted Plaintiff’s failure to meet the
11 standard required under such an attack. Stressing that neither *Hoye* nor *Gonzales* supports
12 Plaintiff’s position, the State in oral argument contended that a pre-enforcement as-applied attack
13 requires a showing of three things, none of which Plaintiff has established: (1) a concrete plan to
14 violate the law; (2) a communicated threat of prosecution; and (3) a history of past prosecution or
15 enforcement of the challenged law.

16 Whether Plaintiff’s Dormant Commerce Clause claim as asserted is likely to succeed
17 depends first on whether that claim is ripe. While allowing pre-enforcement, as-applied
18 challenges, *Gonzalez* does not allow for Plaintiff’s broad request. In *Gonzalez*, the Supreme
19 Court denied a request to find a partial-birth abortion ban facially unconstitutional. Instead, it
20 concluded that an as-applied challenge was the “proper means to consider exceptions” to the law
21 because in such an as-applied challenge “it can be shown that in discrete and well-defined
22 instances a particular condition has or is likely to occur in which the prohibited act must be used.”
23 *Id.* at 167. In the first instance, it is not clear to the Court that *Gonzalez*’ standard applies outside
24 of the narrow context of abortion law. Moreover, *Gonzalez* says nothing about the specificity
25 needed to bring a pre-enforcement as-applied challenge but instead reinforces the general
26 proposition that the court should not reach findings of unconstitutionality based on hypotheticals.²

27 ² Neither does *Hoye v. City of Oakland*, 653 F.3d 835 (9th Cir. 2011) stand for the broad
28 proposition that a party can successfully bring an as-applied pre-enforcement challenge to a

1 As the State articulated in oral argument, the constitutional test for ripeness consists of
2 three parts: (1) a concrete plan to violate the law; (2) a communicated threat of prosecution; and
3 (3) a history of past prosecution or enforcement of the challenged law. *See, e.g., Clark v. City of*
4 *Seattle*, 899 F.3d 802 (9th Cir. 2018) (“Where a plaintiff intends to challenge a statute prior to its
5 enforcement, generalized threats of prosecution do not confer constitutional ripeness. Rather,
6 there must be a genuine threat of imminent prosecution. To determine whether a genuine threat
7 of imminent prosecution exists, we use three factors” (citations and internal quotation marks
8 omitted); *Maldonado v. Morales*, 556 F.3d 1037, 1044 (9th Cir. 2009). Moreover, the “prudential
9 inquiry” concerning ripeness weighs “the fitness of the issue for judicial decision and the
10 hardship to the parties of withholding court consideration.” *Maldonado*, 556 F.3d at 1044
11 (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967), *overruled on other grounds by*
12 *Califano v. Sanders*, 430 U.S. 99 (1977)). The former question includes consideration of whether
13 the issue is purely legal or one that requires factual development. *See San Diego Gun Rights*
14 *Committee v. Reno*, 98 F.3d 1121 (9th Cir. 1996) (not ripe because “the issues in the instant pre-
15 enforcement challenge are not purely legal. A concrete factual situation is necessary to delineate
16 the boundaries of what conduct the government may or may not regulate without running afoul of
17 the Commerce Clause.”) Plaintiff has made no attempt to establish these three constitutional
18 elements nor to discuss the prudential concerns.

19 Even so, applying either *Clarks* three-pronged test or the more general rule as stated in
20 *Gonzalez* to the instant case, Plaintiff has not established a likelihood of success on the merits of
21 its pre-enforcement as-applied challenge because it has not established that the issue is ripe for
22 review. Specifically, Plaintiff has not sufficiently shown that AB 824 is likely to be enforced in
23 an unconstitutional manner, nor has Plaintiff stated neither a plan to violate the law or a specific
24 threat that the law will be enforced in the manner they fear. Plaintiff relies heavily on the

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26 statute under all circumstances. Rather, aside from articulating that a paradigmatic as-applied
27 approach can be appropriate at least in the context of First Amendment jurisprudence, *Hoye* offers
28 little support for Plaintiff’s position and only further confirms that courts “decline[] to entertain
as-applied challenges that would require [them] to speculate as to prospective facts.” *Id.* at 859.

1 declarations it submitted in support of its motion for preliminary injunction. (*See* ECF Nos. 10-
2 2–10-7.) Plaintiff’s briefs make these declarations out to be bold statements that should AB 824
3 go into effect, the subject companies will be forced to make drastic changes to their business
4 practices. However, none of the declarations state an intent to violate AB 824, and none lay out a
5 specific circumstance in which AB 824 will be applied. Instead, the declarants make generalized
6 statements that there are many lawsuits arising from ANDA Paragraph IV applications, that many
7 such lawsuits have settled (it is not clear how many settled with reverse payments), and that AB
8 824 may have some impact on these cases. The declarants claim they will likely be forced to
9 litigate pending patent-infringement lawsuits to judgment out of fear of AB 824’s penalties, even
10 if a procompetitive settlement could be reached. Declarants also claim they may keep the new
11 generics they are currently developing off the market, or will be required to reevaluate their plans,
12 rather than risk the cost of litigation or face AB 824 penalties. But no declarant claims its
13 company has a concrete plan to violate the terms of AB 824. (*See id.*) Had Plaintiff submitted
14 evidence of a currently pending reverse payment settlement negotiation in which the parties
15 would not settle as a result of AB 824 or feared prosecution under AB 824, then this case might
16 be ripe for a pre-enforcement, as-applied challenge. However, that is not the case. Rather, and
17 more to the point regarding prudential ripeness, it is clear to the Court that this is not a purely
18 legal issue, and that additional facts are necessary to address the Commerce Clause question.

19 Because the Court finds Plaintiff’s pre-enforcement as-applied claim under the Dormant
20 Commerce Clause is not ripe for review, the Court finds Plaintiff has not established a likelihood
21 of success on the merits of its claim, nor has Plaintiff raised serious questions going to the merits,
22 and so a preliminary injunction shall not issue on these grounds at this time.³ Even if Plaintiff

23 ³ Plaintiff’s pre-enforcement as-applied challenge is also problematic because it may be
24 construed as an attempt to extend a facial overbreadth challenge outside the First Amendment
25 context. In theory, Plaintiff claims that the language of the law in question is overbroad because
26 it may allow the government to enforce it unconstitutionally. *See, e.g., Sabri v. U.S.*, 541 U.S.
27 600, 609 (2004) (“It would have been correspondingly clear that if Sabri was making any
28 substantive constitutional claim, it had to be seen as an overbreadth challenge; the most he could
say was that the statute could not be enforced against him, because it could not be enforced
against someone else whose behavior would be outside the scope of Congress’s Article I authority
to legislate.”). But under Plaintiff’s logic, any law regarding commerce passed by the California

1 had raised serious questions as to the merits of its Dormant Commerce Clause claim, the balance
2 of hardships does not tip significantly in Plaintiff’s favor, as discussed below, such that a
3 preliminary injunction should be granted.

4 2. Preemption

5 Plaintiff makes two primary arguments concerning preemption. First, Plaintiff asserts AB
6 824 conflicts with the objectives of federal patent law, and specifically the Hatch-Waxman Act.
7 And second, Plaintiff argues AB 824 is directly preempted by both the Patent Act and by the
8 delicate balance struck between antitrust law and patent law, as discussed by the Supreme Court
9 in *FTC v Actavis*, 570 U.S. 136 (2013). For its part, the State asserts that AB 824 does not
10 conflict with federal patent law and notes that Plaintiff does not identify “a specific patent
11 provision with which AB 824 conflicts.” (ECF No. 24 at 7.) The State also contends that AB
12 824 does not conflict with the Hatch-Waxman Act because it will further the goals of the Act, not
13 frustrate them as Plaintiff claims. And finally, the State argues that *Actavis* does not preempt AB
14 824 because it weighed in on the interaction between federal, as opposed to state, antitrust law
15 and patent law and established only that patent settlements were not *per se* exempt from antitrust
16 liability.

17 Plaintiff indeed has not pointed to any provision of the Patent Act that conflicts with AB
18 824 except to assert in oral argument that federal patent law is entitled to field preemption and
19 states cannot create their own patent-like protections. While this assertion is correct, it does not
20 settle the question of preemption presented to this Court. “[S]tate law is preempted when it enters
21 ‘a field of regulation which the patent laws have reserved to Congress.’ Where state law offers
22 ‘patent-like protection for ideas deemed unprotected under the present federal scheme, [state law]
23 conflicts with the strong federal policy favoring free competition in ideas.’” *Summit Mach. Tool*
24 *Mfg. Corp. v. Victor CNC Sys., Inc.*, 7 F.3d 1434, 1439 (9th Cir. 1993) (citing *Bonito Boats, Inc.*

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26 legislature would have to include language specifically limiting its application to within
27 California. That simply cannot be the case, and Plaintiff cites to no authority indicating
28 otherwise. Moreover, *Sabri* cautioned against overbreadth challenges applied outside the scope
of the First Amendment and the Supreme Court has regularly declined to extend such an analysis
to other constitutional challenges. *Id.* at 609–610.

1 *v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 167 (1989)). But AB 824 is not offering patent-like
2 protection; instead it is imposing a presumption of anti-competitiveness on certain types of patent
3 settlements. A state law claim can survive federal patent law preemption so long as the state
4 claim “contains an element not shared by the federal law; an element which changes the nature of
5 the action so that it is qualitatively different from a copyright [or patent] infringement claim.”
6 *Summit Mach. Tool Mfg. Corp. v. Victor CNC Sys., Inc.*, 7 F.3d 1434, 1439–40 (9th Cir. 1993)
7 (internal quotation omitted, brackets in original) (considering state law misappropriation claim in
8 light of federal patent laws). AB 824 does not require a court to determine the validity or
9 invalidity of a patent. Instead, it is focused on the payment of a “thing of value” to the generic
10 drug company and attaches a presumption that such a transfer serves anti-competitive purposes.
11 Because AB 824 does not require determination of the validity of a patent and does not create
12 patent-like protections, it does not conflict with federal patent law and is therefore not preempted
13 under this analysis.

14 Plaintiff’s next assertion that AB 824 conflicts with, and is therefore preempted by, the
15 Hatch-Waxman Act is predicated on Plaintiff’s claim that the ultimate effect of AB 824 will be to
16 stifle the creation, production, and entry onto the market of cheaper generic medications. The
17 State, by contrast, argues that the intent of AB 824 is to ensure that generic drugs are not kept off
18 the market by the practice of reverse payment settlements and banning these settlements will
19 ensure generics enter the market sooner, ultimately decreasing drug prices and protecting the
20 public’s access to affordable medicine. The parties agree that the intent of the Hatch-Waxman
21 Act was to create a pathway for generic medications to enter the market faster and to lower
22 prescription drug prices as a result. The argument of each party turns on how exactly AB 824
23 will impact these goals. Because AB 824 has not been enacted, nor has any other similar law
24 been enacted in another state, it is impossible to know if this law will have its intended effect, or
25 as Plaintiff argues, will backfire, causing generic drug companies to cease filing ANDA
26 applications and challenging patents held by brand-name drug companies. The Court is not in a
27 position to predict the future impacts of AB 824 before it is enacted and enforced. At this time, it
28 is too speculative for the Court to find one way or another that AB 824 will frustrate or further the

1 aims of the Hatch-Waxman Act. As such, Plaintiff cannot show a likelihood of success on the
2 merits of its conflict preemption claim.

3 Finally, Plaintiff argues *Actavis* “went out of its way to protect” (ECF No 10-1 at 22) the
4 delicate balance Congress struck between patent law and antitrust law. Plaintiff contends AB 824
5 disrupts this balance and is therefore preempted by *Actavis*. In support of this assertion, Plaintiff
6 cites *Connell Const. Co. v. Plumbers & Steamfitters Local Union No. 100*, 421 U.S. 616 (1975), a
7 case in which the Supreme Court found that “[b]ecause employee organization is central to
8 federal labor policy and regulation of organizational procedures is comprehensive, federal law
9 does not admit the use of state antitrust law to regulate union activity that is closely related to
10 organizational goals.” In *Connell Construction*, the Supreme Court limited the application of
11 state antitrust law to federal labor laws. In *Actavis*, by contrast, the Supreme Court opened
12 reverse payment patent settlements to antitrust scrutiny rather than limiting the application of
13 antitrust law to patent settlements. Therefore, *Connell Construction* is inapposite.

14 *Actavis*’ holding opens patent settlements to antitrust scrutiny by overturning previous
15 circuit court precedent that reverse payment settlements do not present antitrust concerns “so long
16 as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”
17 570 U.S. at 141 (internal quotes omitted). Instead of following the circuit analysis, *Actavis*
18 applied antitrust law to reverse payment settlements and found that such settlements may violate
19 federal antitrust laws. *Actavis*’ analysis is based not on a presumption of validity of the
20 underlying patent, but rather on the balance between the anti- and pro-competitive impacts of the
21 settlement agreement.

22 Plaintiff notes the California Supreme Court acknowledged that the “United States
23 Supreme Court is the final arbiter of questions of patent law and the extent to which
24 interpretations of antitrust law — whether state or federal — must accommodate patent law’s
25 requirements” *In re Cipro Cases I & II*, 61 Cal. 4th 116, 142 (2015). Plaintiff posits that the
26 finding in *Actavis* therefore precludes California from imposing its own antitrust laws on reverse
27 payment patent settlements. However, the California Supreme Court determined that “the lesson
28 of *Actavis* is that nothing in the patent laws or the Hatch–Waxman Act dictates such a special

1 rule; that a settlement resolves a patent dispute does not immunize the agreement from antitrust
2 attack;” and that if federal antitrust law can weigh the pro- and anti-competitive effects of a patent
3 settlement without “offense to patent law, then so too can the state antitrust law.” *In re Cipro*
4 *Cases I & II*, 61 Cal. 4th at 161. This Court agrees with the California Supreme Court. The
5 holding in *Actavis* allows the enforcement of antitrust law on patent settlements rather than
6 foreclosing such enforcement.

7 Plaintiff argues that because *Actavis* applied a rule of reason test and declined to follow a
8 quick look approach or rely on a presumption, California may not create its own presumption
9 when applying its antitrust law to patent settlements. However, there is no such limitation
10 presented in *Actavis* and, as the California Supreme Court points out, “*Actavis* is not dispositive
11 on matters of state law . . . [i]nterpretations of federal antitrust law are at most instructive, not
12 conclusive, when construing the Cartwright Act, given that the Cartwright Act was modeled not
13 on federal antitrust statutes but instead on statutes enacted by California's sister states around the
14 turn of the 20th century.” *In re Cipro Cases I & II*, 61 Cal. 4th at 142. This Court agrees that
15 *Actavis* turns on questions of antitrust law, not patent law, and federal antitrust law does not
16 preempt state antitrust law. *California v. ARC Am. Corp.*, 490 U.S. 93, 101–02 (1989)
17 (“Congress has not pre-empted the field of antitrust law . . . Congress intended the federal
18 antitrust laws to supplement, not displace, state antitrust remedies.”). Therefore, *Actavis* does not
19 preempt AB 824, nor does it prevent California’s imposition of a law establishing a presumption
20 regarding the anticompetitive nature of reverse payment settlements under its own antitrust
21 statutes.

22 Further, while *Actavis* applies the rule of reason to the analysis of reverse payment
23 settlements under federal antitrust law, it does not establish exactly how and when this test should
24 be applied. Instead, the Court in *Actavis* explicitly leaves the question of how to apply the rule it
25 articulated to the lower courts. “As in other areas of law, trial courts can structure antitrust
26 litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit
27 proper analysis, and, on the other, consideration of every possible fact or theory irrespective of
28 the minimal light it may shed on the basic question — that of the presence of significant

1 unjustified anticompetitive consequences. We therefore leave to the lower courts the structuring
2 of the present rule-of-reason antitrust litigation.” 570 U.S. at 159–60.

3 Plaintiff’s arguments that AB 824 is preempted by federal law are therefore not likely to
4 succeed. As a result, Plaintiff cannot show that there is a likelihood of success on the merits.
5 Further, even if Plaintiff had raised serious questions as to the merits of the preemption question,
6 the balance of hardships does not tip significantly in Plaintiff’s favor, as discussed below, such
7 that a preliminary injunction should be granted.

8 3. Excessive Fines

9 In terms of a penalty, AB 824 imposes a fine against any individual who assists in what is
10 deemed to be a violation of the bill of three times the value received by the individual due to the
11 violation or \$20 million, whichever is greater. By the terms of the bill, this minimum of \$20
12 million applies to any individual who assists in the party’s violation even if that person gained
13 nothing of value as a result of the violation. Presumably, such a penalty could be levied against a
14 junior associate or legal secretary working at the law firm representing one of the settling parties.

15 Plaintiff raises two arguments that AB 824 imposes excessive fines: (1) that the upper
16 threshold of three times the value received is excessive in relation to the purported
17 anticompetitive harms of any violative settlement agreement; and (2) that a minimum fine of \$20
18 million is excessive as it applies to individuals, as opposed to parties. For its part, the State
19 argues, (1) Plaintiff’s claim is not ripe for determination because such a claim is dependent on a
20 number of factual inquiries not presently before the Court; (2) the Court should defer to the State
21 in setting penalties or fixing fines unless they are so grossly excessive as to amount to a due
22 process violation;⁴ and (3) because Plaintiff is bringing a facial attack on AB 824, its claim can
23 only succeed if it shows no set of circumstances exist under which the Act would be valid, which
24 it cannot do.

25 ⁴ The Court acknowledges Plaintiff’s reference to the recent case of *Timbs v. Indiana*, 139
26 S. Ct. 682, 687–89 (2019), which holds the Excessive Fines Clause is fully incorporated against
27 the states. The Court need not and does not determine whether such incorporation revokes the
28 deference otherwise afforded to the State to set penalties and fines. Because the Court finds
Plaintiff’s Excessive Fines claim is unripe, it need not consider the State’s argument for
deference.

1 The parties agree that the Eighth Amendment prohibits states from imposing “excessive
2 fines” and has been applied where the fine is imposed, in whole or in part, as punishment for an
3 offense. The parties also do not dispute that the fine imposed under AB 824 is intended as a
4 penalty and further agree that a fine is considered excessive if it is disproportionate to the gravity
5 of the offense. In the Ninth Circuit, courts consider four factors in determining whether a penalty
6 is grossly disproportionate to the offense: (1) the nature and extent of the violation; (2) whether
7 the violation was related to other illegal activities; (3) other penalties that may be imposed for the
8 violation; and (4) the extent of the harm caused. (ECF No. 10 at 28; ECF No. 24 at 12; *see*
9 *United States v. \$132,245.00 in U.S. Currency*, 764 F.3d 1055, 1058 (9th Cir. 2014)).

10 It is not entirely clear whether Plaintiff intends to raise a facial or as-applied attack against
11 the penalty portion of AB 824. At least with respect to Plaintiff’s claim that the upper threshold
12 is excessive in relation to the purported anticompetitive harms of any violative settlement
13 agreement, Plaintiff’s attack — seeking to invalidate the law (or at least enjoin the penalty
14 provision) as applied to any defendant — is necessarily a facial one. *See Hoye*, 653 F.3d at 857
15 (“Because the difference between an as-applied and a facial challenge lies only in whether all or
16 only some of the statute’s subrules (or fact-specific applications) are being challenged, the
17 substantive legal tests used in the two challenges are ‘invariant.’”) As discussed above, a facial
18 attack of a law is exceedingly difficult to raise successfully. “[T]he Court’s analysis of Plaintiffs’
19 facial excessive fines claims asks whether parts of the penalty structure are always grossly
20 disproportional, or if there are circumstances where the penalties would be valid.” *In re Toll*
21 *Roads Litig.*, No. SACV1600262AGJCGX, 2018 WL 4945314, at *2 (C.D. Cal. July 31, 2018)
22 (citing *United States v. Bajakajian*, 524 U.S. 321, 336 (1998)); *United States v. Salerno*, 481 U.S.
23 739, 745 (1987). Certainly, the Court can fathom a set of circumstances in the context of massive
24 pharmaceutical settlements under which the imposition of three times the value received due to
25 the violation or \$20 million, whichever is greater, might be appropriate. At the most general
26 level, then, Plaintiff’s facial attack again fails.

27 Moreover, and as the parties agree, in evaluating a claim under the Excessive Fines
28 Clause, “the standard of gross disproportionality” requires a court to “compare the amount of the

1 forfeiture to the gravity of the [] offense. If the amount of the forfeiture is grossly
2 disproportional to the gravity of the defendant's offense, it is unconstitutional.” *Bajakajian*, 524
3 U.S. at 336-37. In the Ninth Circuit, this typically requires courts to consider the four factors
4 articulated above: (1) the nature and extent of the violation; (2) whether the violation was related
5 to other illegal activities; (3) other penalties that may be imposed for the violation; and (4) the
6 extent of the harm caused. *See United States v. \$132,245.00 in U.S. Currency*, 764 F.3d 1055,
7 1058 (9th Cir. 2014). Each of these four factors — perhaps with the exception of the third — are
8 all but impossible to assess in the abstract, highlighting the difficulty of a pre-enforcement attack
9 based on the Excessive Fines Clause. As one district court noted, “[t]he first factor requires
10 review of the circumstances of the offense ‘in great detail.’” *Crawford v. United States Dep’t of*
11 *the Treasury*, No. 3:15-CV-250, 2015 WL 5697552, at *14–15 (S.D. Ohio Sept. 29, 2015), (citing
12 *Solem v. Helm*, 463 U.S. 277, 290–91 (1983) (Cruel and Unusual Punishments Clause analysis)).
13 “In this case, there are no circumstances to review, because no . . . penalty has been imposed. A
14 fact-specific determination of excessiveness is impossible where any wrongful conduct is
15 hypothetical.” *Id.* The same is true here.

16 In other words, without examining the factual underpinnings of an *actual violation* the
17 Court can hardly speculate as to the nature and extent of the violation, whether the violation is
18 related to other illegal activities (perhaps unlikely in this scenario, but not impossible), and the
19 extent of the harm caused, if any, as it is yet unknown. Plaintiff’s arguments to the contrary hinge
20 on its position that “run-of-the-mill patent settlements” are not at all harmful, and thus such a
21 pricey penalty is excessive. (*See* ECF No. 10 at 28–29.) But it is not so clear to the Court that the
22 settlements impacted by AB 824 will be “run-of-the-mill.” Quite clearly, the State’s position is
23 that AB 824’s goal is to effect only those settlements that are ultimately harming consumers.
24 Without a factual underpinning by which to assess a violation, it is impossible to know if the
25 upper threshold imposed is excessive. Put simply, the Court is not willing at this point to find the
26 upper threshold of AB 824’s penalty provision is grossly disproportional to the gravity of every
27 conceivable violation of the statute. The Court therefore agrees with the State that Plaintiff’s
28 Excessive Fines claim is not ripe for adjudication as it pertains to Plaintiff’s attack of the upper

1 limit imposed under the statute, and Plaintiff has therefore failed to establish a likelihood of
2 success on the merits of this claim.

3 With respect to the \$20 million minimum, Plaintiff attempts to clarify in reply that
4 “[c]hallenges to limitations that appear on the face of state laws are ripe the moment the
5 challenged law is enacted,” and further that its “principal Excessive Fines claim is that \$20
6 million is excessive as applied to an individual *under any scenario*.” (ECF No. 27 at 12,
7 emphasis in original.) Because Plaintiff seeks to invalidate or enjoin the penalty provision of AB
8 824 as it might be applied to individuals only, the attack is necessarily an as-applied pre-
9 enforcement attack.

10 Plaintiff fails to cite to any authority establishing that an as-applied pre-enforcement claim
11 is cognizable under the Excessive Fines Clause. But assuming it is, the Court must nevertheless
12 apply the three-part test articulated above with respect to pre-enforcement challenges generally.
13 Specifically, in order to successfully establish that the claim is ripe for review, Plaintiff must
14 show: (1) a concrete plan to violate the law; (2) a communicated threat of prosecution; and (3) a
15 history of past prosecution or enforcement of the challenged law. As discussed above with
16 respect to Plaintiff’s claim under the Dormant Commerce Clause, Plaintiff does not sufficiently
17 meet this standard. Even more so with respect to Plaintiff’s “as-applied to individuals” claim,
18 Plaintiff has made no attempt to proffer evidence that a single individual intends to violate AB
19 824, nor that the State has communicated a threat of levying a \$20 million fine against, for
20 example, a junior associate at a law firm who took notes during settlement negotiations. Further,
21 the prudential inquiry leads the Court to find the claim is unripe as it requires factual
22 development. As a result, the Court finds Plaintiff’s pre-enforcement as-applied to individuals
23 attack is not yet ripe, and Plaintiff therefore fails to establish a likelihood of success on the merits
24 of the claim.

25 Lastly, regardless of whether Plaintiff’s Excessive Fines claim is intended as a facial or
26 as-applied attack on the provision as it applies to individuals, any Excessive Fines claim requires
27 a court to consider the four factors articulated above to determine if the fine is disproportionate to
28 the gravity of the offense. Again, those factors are: (1) the nature and extent of the violation; (2)

1 whether the violation was related to other illegal activities; (3) other penalties that may be
2 imposed for the violation; and (4) the extent of the harm caused. *See United States v.*
3 *\$132,245.00 in U.S. Currency*, 764 F.3d 1055, 1058 (9th Cir. 2014); *see also Hoyer*, 653 F.3d at
4 857 (“Because the difference between an as-applied and a facial challenge lies only in whether all
5 or only some of the statute’s subrules (or fact-specific applications) are being challenged, the
6 substantive legal tests used in the two challenges are ‘invariant.’”) In the context of the \$20
7 million fine as applied to individuals, Plaintiff comes closer to establishing possible success on
8 this part of the inquiry. To be sure, the Court is troubled that a law firm’s junior associate could
9 theoretically face a \$20 million fine for her participation in negotiating a settlement agreement
10 that violates AB 824. But given the posture of this case, the Court cannot say Plaintiff has
11 established a likelihood of success, or even raised serious questions going to the merits of its
12 claim. As explained above, the analysis required to find an Excessive Fines Clause violation is
13 fact-specific. Even narrowing the challenge to the statute as it applies to individuals, the Court
14 cannot analyze the circumstances surrounding a violation before any violation occurs. Indeed, if
15 a \$20 million fine is levied against an individual in a case in which the four factors articulated
16 above indicate such a fine is excessive, that individual may apply for a temporary restraining
17 order or injunction and seek to invalidate the law as it is applied unconstitutionally to the
18 individual. Absent those facts, the relief requested is premature. For those reasons, the Court
19 finds Plaintiff has failed to establish a likelihood of success on the merits of its Excessive Fines
20 claim. Further, even if Plaintiff had raised serious questions as to the merits of the claim, the
21 balance of hardships does not tip significantly in Plaintiff’s favor, as discussed below, such that a
22 preliminary injunction should be granted.

23 4. Due Process

24 Finally, Plaintiff argues AB 824 violates due process because (1) it unfairly shifts the
25 burden to the defendant to prove procompetitive effects; (2) the defendant’s opportunity to rebut
26 the presumptions imposed are meaningless because the statute presumes anticompetitive effects;
27 and (3) relatedly, a manufacturer will not be able to prove an agreement *has had* procompetitive
28 effects, even if that agreement *will* generate such effects over time. (ECF No. 10 at 30–31.) In

1 opposition, the State argues: (1) the State has the authority to regulate legal procedure, including
2 establishing a burden; (2) AB 824 expressly provides parties a meaningful opportunity to
3 disprove liability once the burden is appropriately shifted; and (3) Plaintiff’s position that the
4 presumptions set forth in AB 824 represent a stark departure from established law is unsupported.
5 (ECF No. 24 at 24–25.) In reply, Plaintiff seems to concede that a burden shift in and of itself is
6 not violative of due process, clarifying that AB 824 is unconstitutional “because it shifts the
7 burden of persuasion to the defendant *and also* imposes a presumption of guilt while making it
8 effectively impossible to rebut that presumption.” (ECF No. 27 at 13.) More specifically,
9 Plaintiff cites to a scenario in which a generic settles a patent dispute by agreeing to an early but
10 not immediate entry date with an exclusive license. The generic, Plaintiff claims, will have to
11 prove that such an agreement *has* generated procompetitive benefits and that the benefits
12 outweigh the anticompetitive effects presumed by the law. (*Id.*)

13 Again, Plaintiff is not likely to succeed on the merits of this claim. First, Plaintiff cites to
14 no authority holding that the burden of persuasion can never properly be shifted to the defendant
15 to disprove liability, and the Court is aware of none. Indeed, Plaintiff all but concedes that a
16 burden shift in the first instance is not itself a violation of due process. (ECF No. 27 at 9.)
17 Plaintiff’s better argument is that AB 824 does not provide a *meaningful* opportunity to rebut the
18 presumption because it requires a defendant to show the questioned agreement *has already had*
19 procompetitive effects. As the law is written, the fact that a settlement supposedly *will* have
20 procompetitive effects is not sufficient to rebut the antitrust presumption.

21 While seemingly an accurate statement of AB 824’s language, the Court is not convinced
22 that AB 824’s express provision allowing a manufacturer to rebut the presumption by showing
23 procompetitive effects is not meaningful. Here, it is Plaintiff’s burden to establish a likelihood of
24 success on its due process claim. But Plaintiff offers nothing in the way of caselaw or evidence
25 supporting its stance that the process provided for by the statute is not meaningful. First, there are
26 other means of disproving liability, including showing the value received is fair and reasonable
27 compensation solely for other goods or services provided. Also, the parties remain free to invoke
28 any other standard antitrust defense. And moreover, the fact that AB 824 demands a showing that

1 a settlement “has directly generated procompetitive benefits”⁵ does not render that option
2 meaningless. Indeed, the Court can imagine a scenario where a settlement would have an
3 immediately procompetitive effect. AB 824 simply reflects a desire to penalize parties that enter
4 into agreements that — among other requirements — have not generated procompetitive benefits.

5 To the same point, Plaintiff overstates the changes AB 824 makes to established
6 jurisprudence in the areas of antitrust and patent law. The presumption raised by AB 824 is
7 stronger, and the burden shift may be sharper, but both federal and state antitrust caselaw
8 provides for a similar presumption and burden shift in the context of reverse payment settlement
9 agreements. *See FTC v. Actavis*, 570 U.S. 136 (2013); *In re Cipro Cases I & II*, 348 P.3d 845
10 (Cal. 2015). And both federal and state cases make clear that, (1) agreements must be assessed as
11 of the time they are made; and (2) the relevant baseline for determining whether an agreement is
12 procompetitive is the period of competition that would have been, but for the settlement (as
13 opposed to using the life of a valid patent as a baseline). *See In re Cipro*, 348 P.3d at 158. As set
14 forth in *In re Cipro*, “Antitrust law condemns the purchase of freedom from competition; what
15 matters is whether a settlement postpones market entry beyond the average point that would have
16 been expected at the time in the absence of agreement.” 348 P.3d at 159. Importantly, AB 824
17 provides a mechanism — indeed more than one — by which a defendant can rebut the
18 presumption arising from a reverse payment settlement. Nothing supports the contention that this
19 mechanism is not meaningful simply because it requires an actual showing of procompetitive
20 benefits as of the time the settlement is entered,⁶ as opposed to some level of speculation that
21 procompetitive benefits will result at some undetermined time in the future.

22 Finally, Plaintiff asserts AB 824’s presumption that the relevant product market is limited
23 to the branded drug and its generic substitutes renders the anticompetitive presumption

24 ⁵ The State cites to *In re Cipro Cases I & II*, 348 P.3d 845 at 149–150 (Cal. 2015), to
25 support its contention that this language “draws on established antitrust jurisprudence and the ex
26 ante framework of pay-for-delay jurisprudence.” This “has directly generated” language does not
27 appear in *Cipro*.

28 ⁶ The Court has no way of knowing how immediate AB 824 enforcement may be after entry
of settlement.

1 irrebuttable because it deprives defendants of the opportunity to present every available defense.
2 (ECF No. 10 at 39.) The Court disagrees. AB 824 simply erects a presumption regarding the
3 relevant market. It does not foreclose the defendant from presenting evidence that the relevant
4 market is broader than the one presumed. Granted, AB 824 seems to stack certain presumptions
5 on top of other presumptions. This may have the effect of making it more difficult to rebut all
6 applied presumptions, but nothing indicates to the Court that it has the effect of depriving
7 potential defendants of their due process rights. As a result, the Court finds Plaintiff has not
8 established a likelihood of success on the merits of its due process claim, nor has it raised serious
9 questions going to those merits. Even if Plaintiff had raised serious questions, as discussed
10 below, the balance of hardships does not tip significantly in Plaintiff's favor such that a
11 preliminary injunction should be granted.

12 *B. Irreparable Injury*

13 Because the Court finds Plaintiff is not likely at this time to succeed on the merits of any
14 of its claims, it need not address the remaining *Winter* factors. *See Alliance for the Wild Rockies*,
15 632 F.3d at 1135 (A plaintiff must “make a showing on all four prongs” of the *Winter* test to
16 obtain a preliminary injunction.). Nonetheless, the Court briefly discusses the remaining factors,
17 which further support that issuance of a preliminary injunction is not justified at this time.

18 Plaintiff alleges its members will suffer irreparable injury because: (1) AB 824 violates
19 Plaintiff's members' constitutional rights and they are therefore *per se* irreparably injured; (2)
20 they will be forced to make a decision to either continually violate AB 824 and expose
21 themselves to significant liability or litigate every patent dispute to judgment and carry the
22 financial burden of doing so; and (3) as a result of AB 824 and the impossible choice presented
23 by (2), Plaintiff's members will have no choice but to cease entering the market, leading to lost
24 goodwill and damage to reputation. Moreover, Plaintiff asserts its members will be irreparably
25 harmed by the imposition of a fine pursuant to AB 824 because the Eleventh Amendment
26 prohibits parties from suing state officials, and therefore prevents recoupment of any unjustified
27 payment. In response, the State emphasizes that Plaintiff's claimed injuries are purely
28 speculative, and that any potential harm to Plaintiff's members will be the result of their own

1 business choices, not the result of AB 824 itself. The State also argues that because Plaintiff has
2 failed to demonstrate a likelihood of success on the merits of its constitutional claims, it has failed
3 to demonstrate that it will suffer irreparable harm resulting from a constitutional violation.

4 The State is of course correct that absent a likelihood of success on the merits of its
5 constitutional claims, Plaintiff's claimed *per se* injury resulting from a constitutional violation
6 necessarily fails. As for Plaintiff's other claimed injuries, the Court finds Plaintiff overstates the
7 certain and impending harm AB 824 will do. First, AB 824 does not prohibit patent settlements;
8 the claim that AB 824 will force Plaintiff's members to either violate the law or litigate to
9 judgment, both at great expense, is therefore based on speculation of how companies will choose
10 to react to AB 824's implementation. But at least one FTC report indicates the majority of patent
11 settlements do not contain a reverse payment at all. (*See* ECF No. 24 at 19, citing *Overview of*
12 *Agreements Filed in FY 2016*, A Report by the FTC Bureau of Competition.) Surely, then,
13 parties to pharmaceutical patent litigation *can* settle in the aftermath of AB 824.

14 Moreover, “[s]peculative injury does not constitute irreparable injury sufficient to warrant
15 granting a preliminary injunction.” *Caribbean Marine Servs. Co. v. Baldrige*, 844 F.2d 668, 674
16 (9th Cir. 1988) (citing *Goldie's Bookstore, Inc. v. Super. Ct.*, 739 F.2d 466, 472 (9th Cir.1984)).
17 “A plaintiff must do more than merely allege imminent harm sufficient to establish standing; a
18 plaintiff must demonstrate immediate threatened injury as a prerequisite to preliminary injunctive
19 relief.” *Id.* (citing *Los Angeles Memorial Coliseum Commission v. National Football League*,
20 634 F.2d 1197, 1201 (9th Cir.1980)). As discussed above in the context of Plaintiff's Dormant
21 Commerce Clause claim, nowhere does Plaintiff point to a specific pending case or settlement
22 negotiation in which it will need to act differently as a result of AB 824 (nor is the Court
23 convinced that a change in a drug manufacturer's business practices would constitute irreparable
24 harm in any event). Speculation of how the market will react to the bill's implementation is not
25 enough to support a preliminary injunction.

26 Most concerning to the Court is Plaintiff's claim that any fine improperly levied —
27 especially with respect to an individual — could not be recouped because of the Eleventh
28 Amendment's protection of state officials. But at this time, that injury is also speculative and not

1 imminent. Indeed, if the State were to pursue a \$20 million fine against a minor individual
2 participant in a violative settlement agreement, for example, that individual may be able to state a
3 claim that the law violates the Excessive Fines Clause as applied to them and may be able to seek
4 a preliminary injunction on those grounds. That, however, is not presently before the Court.

5 *C. Balance of Hardships and Public Interest*

6 The last two factors of the *Winter* test are: “[] that the balance of equities tips in
7 [plaintiff’s] favor, and [] that an injunction is in the public interest.” *Winter*, 555 U.S. at 20.
8 “When the government is a party, these last two factors merge.” *Drakes Bay Oyster Co. v.*
9 *Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). Therefore the Court must analyze the balance
10 between the hardships imposed on AAM and its members and the impact an injunction on the
11 enforcement of AB 824 will have on the public. It is true that there may be some costs and
12 changes to the business practices of Plaintiff’s members as a result of AB 824; however, as
13 discussed above, Plaintiff has failed to establish irreparable injury because its claimed injuries are
14 based purely on speculation as to how members might react to the new law. For the same
15 reasons, the analysis of the burden imposed on Plaintiff therefore does not tip the scale heavily in
16 Plaintiff’s favor.

17 As for the public interest, this factor is at best neutral as both parties argue AB 824 will
18 have the opposite effect. Plaintiff argues that not only does AB 824 impose significant burdens
19 on it and its members, but also that the enforcement of AB 824 is not in the interest of the public.
20 Plaintiff posits that should AB 824 go into effect, generic drug companies will be forced to
21 litigate patent disputes to resolution, significantly increasing litigation costs, decreasing budgets
22 for development of new generic drugs, and thereby decreasing the public’s access to cheaper
23 generic drug alternatives. Plaintiff also foresees generic drug companies refraining from putting
24 any new generics on the market to avoid litigation or liability under AB 824, similarly limiting
25 access to generic alternatives and increasing the cost of prescription drugs on the whole.

26 The State, by contrast, asserts that AB 824 will lower prescription drug prices by closing a
27 loophole in the Hatch-Waxman Act whereby brand-name drug companies are able to preserve
28 otherwise weak patents by paying generic drug companies to keep their drugs off the market.

1 Under the State's analysis, closing this loophole will ensure that generic and brand companies no
2 longer have an incentive to keep the generic off the market for longer than would be supported by
3 the underlying patent and thus encourage the entry of cheaper generics onto the market faster.
4 According to the State, AB 824 is designed to curb the high costs of prescription drugs.

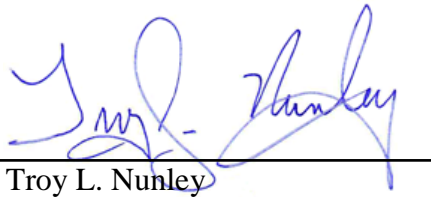
5 At this juncture, how AB 824 will impact the public interest is purely speculative. The
6 Court cannot predict how the market will react to this new law, nor should it. There is no
7 comparable law in another state nor under federal law, so the Court has no facts before it to base
8 such a determination. Therefore, the balance of equities does not tip in one direction or the other,
9 and it certainly does not tip sharply in Plaintiff's favor. Thus, this factor does not support the
10 imposition of an injunction against the enforcement of AB 824.

11 **VI. CONCLUSION**

12 Based on the foregoing, Plaintiff's Motion for Preliminary Injunction (ECF No. 10) is
13 DENIED. Such denial is without prejudice to Plaintiff seeking another preliminary injunction
14 should certain facts develop and/or certain claims become ripe during the pendency of this
15 litigation.

16 IT IS SO ORDERED.

17 Dated: December 31, 2019

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21 Troy L. Nunley
22 United States District Judge
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