

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

ASSOCIATION FOR ACCESSIBLE
MEDICINES,

Plaintiff,

v.

ROB BONTA, in his official capacity as
Attorney General of the State of California,

Defendant.

No. 2:20-cv-01708-TLN-DB

ORDER

This matter is before the Court on Plaintiff Association for Accessible Medicine's ("Plaintiff") Motion for Preliminary Injunction ("PI") requesting the Court enjoin the enforcement of Assembly Bill 824 ("AB 824"). (ECF No. 15.) Defendant Rob Bonta, in his official capacity as Attorney General of the State of California ("Defendant" or the "State"), has filed an opposition.¹ (ECF No. 20.) Plaintiff has filed a reply. (ECF No. 26.) For the reasons set forth below, Plaintiff's motion is GRANTED.

¹ Pursuant to Federal Rule of Civil Procedure ("Rule") 25(d), "[t]he officer's successor is automatically substituted as a party" when a public officer "ceases to hold office while the action is pending." Fed. R. Civ. P. 25(d). Accordingly, Rob Bonta is automatically substituted as a party for Xavier Becerra, the former Attorney General of the State of California. The Clerk of the Court is directed to update the docket as necessary.

1 **I. FACTUAL AND PROCEDURAL BACKGROUND²**

2 AB 824, signed into law by California Governor Gavin Newsom on October 7, 2019,
3 creates a presumption that “reverse payment” settlement agreements regarding patent
4 infringement claims between brand-name and generic pharmaceutical companies are anti-
5 competitive and unlawful.

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

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

24 Settlements of the resulting lawsuits sometimes include reverse payments in which the
25 plaintiff, the brand-name company, pays the defendant, the infringing generic company, a sum of
26

27 ² The following factual background is taken mostly verbatim from the Court’s December
28 31, 2019 Order denying Plaintiff’s motion for preliminary injunction in the related case. (*See*
ECF No. 29, No. 2:19-cv-02281-TLN-DB.)

1 money for the promise that the generic company will keep its drug off the market for an agreed-
2 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 a brand-name company cannot continue to
5 enforce an otherwise weak patent against generic companies through these reverse payment
6 settlement agreements. AB 824 imposes a presumption that a settlement agreement involving a
7 brand-name company compensating the generic company for keeping its drug off the market is
8 anticompetitive under California antitrust law. It also levies a civil penalty against any individual
9 who assists in the violation of the section of three times the value received by the individual due
10 to the violation or \$20 million, whichever is greater.

11 Plaintiff, a nonprofit, voluntary association comprised of the leading manufacturers and
12 distributors of generic and biosimilar medicines, manufacturers and distributors of bulk active
13 pharmaceutical ingredients, and suppliers of other goods and services to the generic and
14 biosimilar pharmaceutical industry, previously filed suit in an attempt to invalidate AB 824.
15 (ECF No. 1, No. 2:19-cv-02281-TLN-DB.) In the related case, Plaintiff also filed a motion for
16 preliminary injunction (ECF No. 10, No. 2:19-cv-02281-TLN-DB), which the Court denied (ECF
17 No. 29, No. 2:19-cv-02281-TLN-DB). The Court found, primarily due to the nature of Plaintiff's
18 pre-enforcement attack on AB 824, Plaintiff failed to establish a likelihood of success on the
19 merits or raise serious questions going to the merits. (*Id.*) The Court concluded that absent a
20 constitutional violation, Plaintiff failed to establish an irreparable harm that was both likely and
21 imminent. (*Id.*) Plaintiff subsequently filed an interlocutory appeal of the Court's decision to the
22 Ninth Circuit. (ECF No. 31, No. 2:19-cv-02281-TLN-DB.) The Ninth Circuit heard oral
23 arguments on the matter and ultimately vacated this Court's order and remanded with instructions
24 to dismiss without prejudice, finding Plaintiff failed to demonstrate its members had an Article III
25 injury in fact and concluding Plaintiff lacked associational standing to bring claims on its
26 members' behalf. (*See* ECF Nos. 46–47, No. 2:19-cv-02281-TLN-DB.) The Court subsequently
27 dismissed the suit without prejudice pursuant to the Ninth Circuit's memorandum and mandate.
28 (ECF Nos. 48–49, No. 2:19-cv-02281-TLN-DB.)

On August 25, 2020, Plaintiff filed the instant Complaint alleging near-identical causes of action to its prior suit, once again in an attempt to invalidate AB 824: (1) Declaratory/Injunctive Relief — Commerce Clause — Extraterritoriality; (2) Declaratory/Injunctive Relief — Preemption; (3) Declaratory/Injunctive Relief — Excessive Fines Clause; and (4) Declaratory/Injunctive Relief — Due Process — Burden-Shifting. (ECF No. 1 at 21–33.) On September 14, 2020, Plaintiff filed the instant motion for preliminary injunction. (ECF No. 15.) On October 15, 2020, the State filed an opposition (ECF No. 20), and on October 22, 2020, Plaintiff filed a reply (ECF No. 26).

II. STANDARD OF LAW

Injunctive relief is “an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008) (citing *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam)). “The purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held.” *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981); *see also Costa Mesa City Emps. Ass’n v. City of Costa Mesa*, 209 Cal. App. 4th 298, 305 (2012) (“The purpose of such an order is to preserve the status quo until a final determination following a trial.”); *GoTo.com, Inc. v. Walt Disney, Co.*, 202 F.3d 1199, 1210 (9th Cir. 2000) (“The status quo ante litem refers not simply to any situation before the filing of a lawsuit, but instead to the last uncontested status which preceded the pending controversy.”).

“A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest.” *Winter*, 555 U.S. at 20. A plaintiff must “make a showing on all four prongs” of the *Winter* test to obtain a preliminary injunction. *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135 (9th Cir. 2011). In evaluating a plaintiff’s motion for preliminary injunction, a district court may weigh the plaintiff’s showings on the *Winter* elements using a sliding-scale approach. *Id.* A stronger showing on the balance of the hardships may support issuing a preliminary injunction even where the plaintiff shows that there are “serious questions on the merits . . . so long as the

1 plaintiff also shows that there is a likelihood of irreparable injury and that the injunction is in the
 2 public interest.” *Id.* Simply put, plaintiffs must demonstrate, “that [if] serious questions going to
 3 the merits were raised [then] the balance of hardships [must] tip[] sharply” in [p]laintiffs’ favor
 4 in order to succeed in a request for preliminary injunction. *Id.* at 1134–35.

5 **III. ANALYSIS³**

6 Plaintiff argues in the instant motion for preliminary injunction that it is likely to succeed
 7 on the merits of its claims, its members will suffer irreparable harm absent an injunction, the
 8 balance of equities and the public interest weigh in favor of an injunction, and it is likely to
 9 succeed on the merits. (*See* ECF No. 15-1.) The Court will first address the State’s evidentiary
 10 objections, then the jurisdictional prerequisite of standing, and finally evaluate each of Plaintiff’s
 11 arguments, starting with the dormant Commerce Clause claim.

12 **A. The State’s Objections to Plaintiff’s Evidence**

13 The State filed objections to Plaintiff’s declarations submitted with the instant motion.
 14 (ECF No. 24-1.) With respect to Exhibit E, the State contends the following portion of paragraph
 15 four is inadmissible on the grounds of lack of personal knowledge, in violation of Federal Rule of
 16 Evidence 602: “[B]ecause of [the company’s] concern about the enforcement of AB 824 as it
 17 would apply to such a settlement in light of AB 824’s provision deeming exclusive licenses to be
 18 things of value, [the company] decided to pull out of the settlement negotiation and instead
 19 continue litigating the case.” (*Id.* at 3–4, 6.) The Court finds that Exhibit E contains the sworn
 20 statements of the company’s general counsel, who states that he is “knowledgeable about [the

21 ³ The State requests the Court take judicial notice of Exhibits A through E, Assembly
 22 Committee on Health AB 824 Bill Analysis (March 26, 2019), Assembly Floor Analysis of AB
 23 824 (September 4, 2019), Letters of Support for AB 824, Table 8: Total All Payers State
 24 Estimates by State of Residence (1991-2004) — Drugs and Other Non-durable Products (Millions
 25 of Dollars), Health expenditures by state of residence: Summary tables, and *Pay-for-Delay: How*
 26 *Drug Company Pay-Offs Cost Consumers Billions*, FTC Staff Study (Jan. 2010), respectively.
 (ECF No. 20-1.) Plaintiff has not filed an opposition to this request. The Court previously took
 judicial notice of these exact documents in the prior suit (ECF No. 29 at 5–6, No. 2:19-cv-02281-
 TLN-DB) and for the same reasons now GRANTS the State’s request for judicial notice.

27 The Court has also reviewed and considered the amici curiae brief submitted by the
 28 American Antitrust Institute, Consumer Reports, Inc., and Public Citizen, Inc. in support of AB
 824’s implementation and enforcement. (*See* ECF Nos. 19-2, 22.)

1 company's] recent and pending patent-infringement litigation.” (ECF No. 17-3 at 1–2.) Exhibit
2 E also contains information about the company filing suit against a generic drug company after it
3 filed an ANDA with a Paragraph IV certification challenging one of the company's patents. (*Id.*)
4 The Court sees no reason — and the State has not provided an adequate reason — not to take
5 declarant's statement as truth. The language of the declaration does not indicate “speculation
6 without foundation in personal knowledge,” a basis upon which courts have stricken declarations.
7 *See Green v. City & Cnty. of S.F.*, No. 17-cv-00607-TSH, 2021 WL 3810243 (N.D. Cal. Aug. 21,
8 2021). Further, the declaration states facts that would be admissible evidence. Accordingly, the
9 State's objection with respect to Exhibit E is overruled.

10 The Court need not address objections to evidence upon which it did not rely in the instant
11 motion and therefore declines to consider the State's remaining objections.

12 B. Standing

13 As previously noted, the Ninth Circuit held that Plaintiff lacked associational standing to
14 bring claims on its members' behalf and remanded to this Court to dismiss without prejudice.
15 (*See* ECF Nos. 46–47, No. 2:19-cv-02281-TLN-DB.) Specifically, the Ninth Circuit found none
16 of the declarations submitted from Plaintiff's members alleged an intention to engage in a “pay
17 for delay” settlement agreement “of the sort prohibited by AB 824” and therefore Plaintiff did not
18 establish standing “based on a threat of imminent or certainly impending prosecution.” (ECF No.
19 47 at 5; No. 2:19-cv-02281-TLN-DB (internal quotation marks and citation omitted).) The Ninth
20 Circuit also found Plaintiff's members “have not established that they have incurred economic
21 injury due to complying with AB 824, i.e., by foregoing pay for delay settlement agreements or
22 litigating patent-infringement suits to judgment.” (*Id.*) As the previously-referenced declarations
23 stated the members would only be *likely* to litigate every pending lawsuit to judgment or *likely* to
24 keep their products off-market until the relevant patents expire, the court found Plaintiff alleged
25 “only possible future injury and d[id] not establish a substantial risk of harm.” (*Id.* at 6 (internal
26 quotation marks and citation omitted).)

27 Plaintiff argues in the instant motion that “[a]ny questions of standing or ripeness are now
28 answered” because declarations filed with its motion state that a number of its members have

1 suffered “concrete economic harm.” (ECF No. 15-1 at 8.) In opposition, the State contends
2 Plaintiff has not met its burden to demonstrate Article III standing because it does not
3 demonstrate injury-in-fact and traceability. (ECF No. 20 at 12.)

4 To establish Article III standing, a plaintiff must have “(1) suffered an injury in fact, (2)
5 that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be
6 redressed by a favorable judicial decision.” *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016).
7 “[A]n association has standing to bring suit on behalf of its members when: (a) its members
8 would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are
9 germane to the organization’s purpose; and (c) neither the claim asserted nor the relief requested
10 requires the participation of individual members in the lawsuit.” *Hunt v. Wash. State Apple*
11 *Advert. Comm’n*, 432 U.S. 333, 343 (1977).

12 With respect to injury-in-fact, the State argues “it is not clear whether the potential
13 settlements that [Plaintiff] describes in its declarations even come within the ambit of AB 824” as
14 “one declaration makes no mention of an agreement to forego anything . . . such as sales or
15 research,” “other declarations use generic descriptors such as ‘[Most Favored Nations]’ and
16 ‘industry-standard accelerator provision’ to describe key settlement provisions,” and some of the
17 terms in the declarations “may be subject to exceptions to AB 824.” (*Id.* at 12–13.) Additionally,
18 the State asserts Plaintiff cannot establish standing based on “fears of hypothetical future harm,”
19 such as an altered course of patent settlement negotiations or how the State will enforce AB 824.
20 (*Id.* at 13–14.) However, Plaintiff specifies that Exhibit E, the declaration of one of its members,
21 avers that “the member recently decided, in light of AB 824’s provision deeming exclusive
22 licenses to be things of value (and at considerable cost in terms of legal fees), to pull out of a
23 tentative settlement agreement under which the defendant would have received consideration and
24 would have been allowed to bring its generic product onto the market prior to the expiration of
25 the patent, but not immediately.” (ECF No. 26 at 5 (internal quotation marks omitted) (citing
26 ECF No. 15-6 ¶¶ 4–5).) The declaration further states that “because of [the company’s] concern
27 about the enforcement of AB 824 as it would apply to such a settlement in light of AB 824’s
28 provision deeming exclusive licenses to be things of value, [the company] decided to pull out of

1 the settlement negotiation and instead continue litigating the case.” (ECF No. 17-3 at 3.) The
2 declaration also notes the company “has thus chosen to continue litigating a patent-infringement
3 lawsuit at considerable cost in terms of legal fees that it would not be incurring had the settlement
4 proposal . . . been finalized.” (*Id.*) This declaration avers that the company “intend[ed] to enter
5 into a settlement agreement of the sort prohibited by AB 824” and establishes economic injury in
6 the form of “foregoing pay for delay settlements” — the previous deficiencies identified by the
7 Ninth Circuit. It is therefore sufficient to prove injury-in-fact.

8 With respect to traceability, the Court finds that the injury-in-fact complained of in
9 Exhibit E is directly traceable to AB 824 taking effect at the start of 2020. With respect to
10 redressability, Plaintiff seeks an injunction to stop enforcement of AB 824. (*See* ECF Nos. 1, 15-
11 1.) Accordingly, the Court finds Plaintiff has sufficiently alleged the elements of associational
12 standing to bring the instant motion for preliminary injunction.

13 C. Likelihood of Success on the Merits

14 Plaintiff argues AB 824: violates the dormant Commerce Clause by directly regulating
15 out-of-state-conduct; is preempted by federal patent law, the delicate balance between the
16 competing interests of patent protections and antitrust law struck by the Supreme Court in *FTC v.*
17 *Actavis, Inc.*, 570 U.S. 136 (2013), and the Biologics Price Competition and Innovation Act
18 (“BPCIA”); violates the constitutional prohibition on excessive fines under the Eighth
19 Amendment; and violates due process in that it creates a burden-shift with no meaningful
20 opportunity to rebut the presumption applied. (*See* ECF No. 15-1.) Because the Court finds that
21 Plaintiff is likely to succeed on the merits of its dormant Commerce Clause claim, it will address
22 that claim only and decline to consider the rest of Plaintiff’s arguments challenging the legality of
23 AB 824. Plaintiff argues its dormant Commerce Clause claim is ripe and likely to succeed on the
24 merits. (ECF No. 15-1 at 13–16.) The Court will consider each of Plaintiff’s arguments in turn.

25 i. *Ripeness*

26 Plaintiff contends the issue is ripe for adjudication because (1) the State admitted in oral
27 argument before the Ninth Circuit that it intends to enforce the statute with respect to agreements
28 made out-of-state and (2) Plaintiff’s members have suffered economic injury in the form of

1 declining or losing favorable settlement offers and spending huge sums litigating cases they
2 otherwise would have settled. (ECF No. 15-1 at 13–14.) With respect to prudential ripeness,
3 Plaintiff asserts its claim is now ripe because its members have already suffered economic injury.
4 (*Id.* at 14.)

5 In opposition, the State contends the claim is constitutionally unripe because: Plaintiff has
6 not shown any of its members has a plan to violate the law or has executed the type of agreement
7 prohibited by AB 824 as its declarations fail to “indicate whether California sales would be
8 included in the alleged potential settlements”; statements made by the State during oral argument
9 before the Ninth Circuit do not constitute a threat of prosecution; and Plaintiff does not show past
10 prosecution or enforcement of the law. (ECF No. 20 at 16.) The State characterizes the claim as
11 a pre-enforcement, as-applied claim that is prudentially unripe because it is not yet factually
12 developed and requires the Court to speculate about hypothetical cases as to how AB 824 may be
13 enforced. (*Id.* at 16–17.)

14 The constitutional test for ripeness consists of three parts: (1) a concrete plan to violate the
15 law; (2) a communicated threat of prosecution; and (3) a history of past prosecution or
16 enforcement of the challenged law. *See, e.g., Clark v. City of Seattle*, 899 F.3d 802 (9th Cir.
17 2018). However, Plaintiff is correct that the Court need not rely on this test when “tangible
18 economic injury is alleged,” as “the gravamen of the suit is economic injury rather than
19 threatened prosecution.” *See Nat’l Audubon Society, Inc. v. Davis*, 307 F.3d 835, 855 (9th Cir.
20 2002). Courts then apply the test for Article III standing, *id.* at 855–56, as articulated above. As
21 previously noted, the Court finds Plaintiff adequately establishes constitutional standing.

22 Prudential ripeness is a doctrine that encompasses three principles: “the general
23 prohibition on a litigant’s raising another person’s legal right[;] the rule barring adjudication of
24 generalized grievances more appropriately addressed in the representative branches[;] and the
25 requirement that a plaintiff’s complaint fall within the zone of interests protected by the law
26 invoked.” *Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 127 (2014)
27 (internal quotation marks and citation omitted). The Ninth Circuit has articulated that prudential
28 ripeness involves evaluation of “the fitness of the issues for judicial decision and the hardship to

the parties of withholding court consideration.” *Thomas v. Anchorage Equal Rights Comm’n*, 220 F.3d 1134, 1141 (9th Cir. 2000) (internal quotation marks and citation omitted) (finding plaintiffs’ claims “unfit for judicial resolution” because they were “devoid of any specific factual context” and the record was “remarkably thin and sketchy, consisting only of a few conclusory affidavits”). Here, as previously noted, Exhibit E avers that one of Plaintiff’s member companies decided to pull out of a settlement negotiation for a pay-for-delay settlement agreement and chose instead to continue litigating a patent-infringement lawsuit at significant cost due to concerns about enforcement of AB 824. (ECF No. 17-3 at 3.) Accordingly, the Court finds the claim is prudentially ripe, as there is a sufficient factual development for judicial resolution.

ii. *Likelihood of Success*

Plaintiff argues AB 824 — because it is not limited to settlement agreements entered into in California or between California entities — directly regulates out-of-state commerce and is therefore a per se violation of the dormant Commerce Clause. (ECF No. 15-1 at 14–16 (citing *Baldwin v. G.A.F. Seeling, Inc.*, 294 U.S. 511 (1935); *Sam Francis Found. v. Christies, Inc.* (*Sam Francis*), 784 F.3d 1320 (9th Cir. 2015)).) In opposition, the State contends Plaintiff’s dormant Commerce Clause claim rests solely on an extraterritoriality theory and “the Supreme Court has rarely held that statutes violate the extraterritoriality doctrine.”⁴ (ECF No. 20 at 17 (quoting *Rocky Mountain Farmers Union v. Corey* (*Rocky Mtn.*), 730 F.3d 1070, 1101 (9th Cir. 2013)).) The State maintains AB 824 does not regulate conduct occurring wholly outside California, as an agreement “to engage in unlawful sales in California [that] may be made outside the state does not put those decisions out of the state’s reach.” (*Id.* at 18–19.)

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⁴ The Court agrees with the State that Plaintiff alleges that AB 824 unlawfully regulates extraterritorial activity — especially in light of the fact that the Ninth Circuit has identified the case law Plaintiff cites as pertaining to extraterritoriality arguments and that Plaintiff does not argue any other theory in its briefing. (ECF No. 15-1 at 14–16 (citing *Healy v. Beer Inst.*, 491 U.S. 324, 332 (1989); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.* (*Brown-Forman*), 476 U.S. 573, 579 (1986)); *see also* ECF Nos. 15-1, 26); *Rocky Mtn.*, 730 F.3d at 1101 (citing *Healy*, 491 U.S. at 336; *Brown-Forman*, 476 U.S. at 579). Accordingly, this Court will only address the argument regarding extraterritoriality.

1 The Commerce Clause provides that “Congress shall have power . . . [t]o regulate
2 Commerce . . . among the several States.” U.S. Const., art. I, § 8, cl. 3. “This affirmative grant of
3 power does not explicitly control the several states, but it ‘has long been understood to have a
4 ‘negative’ aspect that denies the States the power unjustifiably to discriminate against or burden
5 the interstate flow of articles of commerce.” *Rocky Mtn.*, 730 F.3d at 1087 (quoting *Or. Waste*
6 *Sys., Inc. v. Dep’t of Env’tl Quality of State of Or.*, 511 U.S. 93, 98 (1994); *Wyoming v.*
7 *Oklahoma*, 502 U.S. 437, 454 (1992)). The “negative” or “dormant” Commerce Clause
8 “prohibits discrimination against interstate commerce and bars state regulations that unduly
9 burden interstate commerce.” *Id.*; *Sam Francis*, 784 F.3d at 1323 (internal citation omitted). The
10 Supreme Court has articulated a two-tiered approach to evaluate state economic regulation under
11 the Commerce Clause: “[1] When a state statute directly regulates or discriminates against
12 interstate commerce, or when its effect is to favor in-state economic interests over out-of-state
13 interests, [the Court has] generally struck down the statute without further inquiry. [2] When,
14 however, a statute only has indirect effects on interstate commerce and regulates evenhandedly,
15 [the Court has] examined whether the [s]tate’s interest is legitimate and whether the burden on
16 interstate commerce clearly exceeds the local benefits.” *Ass’n des Eleveurs de Canards et d’Oies*
17 *du Quebec v. Harris*, 729 F.3d 937, 948 (9th Cir. 2013) (quoting *Brown-Forman Distillers Corp.*
18 *v. N.Y. State Liquor Auth.*, 476 U.S. 573, 578–79 (1986)).

19 With respect to direct regulation of interstate commerce occurring wholly outside of a
20 state’s borders, also known the extraterritoriality doctrine, the dormant Commerce Clause
21 provides that “any ‘statute that directly controls commerce occurring wholly outside the
22 boundaries of a State exceeds the inherent limits of the enacting State’s authority.’” *Rocky Mtn.*,
23 730 F.3d at 1101 (quoting *Healy v. Beer Instit.*, 49 U.S. 324, 336 (1989)). The critical inquiry “is
24 whether the practical effect of the regulation is to control conduct beyond the boundary of the
25 state.” *Id.* (quoting *Healy*, 49 U.S. at 336; *Brown-Forman*, 476 U.S. at 579). To determine
26 practical effect, the Ninth Circuit considers the direct consequences of the statute as well as “how
27 the challenged statute may interact with the legitimate regulatory regimes of other States and
28 what effect would arise if not one, but many or every, State adopted similar legislation.” *Id.*

1 (quoting *Healy*, 49 U.S. at 336). “[T]he Supreme Court has rarely held that statutes violate the
2 extraterritoriality doctrine.” *Id.*

3 Nevertheless, the Ninth Circuit in *Sam Francis* recently found California’s Resale Royalty
4 Act’s clause regulating sales outside the state of California facially violative of the dormant
5 Commerce Clause. 784 F.3d at 1322. The language of the clause at issue required the payment
6 of royalties to the artist after a sale of fine art whenever the seller resided in California or the sale
7 took place in California. *Id.* The court noted the statute violates the dormant Commerce Clause
8 because it “facially regulates a commercial transaction that ‘takes place wholly outside of the
9 State’s borders.’” *Id.* at 1323–24 (citing *Healy*, 491 U.S. at 336; *Valley Bank of Nev. v. Plus Sys.,*
10 *Inc.*, 914 F.2d 1186, 1189–90 (9th Cir. 1990) (“Direct regulation occurs when a state law directly
11 affects transactions that take place . . . entirely outside of the state’s borders. Such a statute is
12 invalid per se”)). The court provided the following example: “if a California resident has a
13 part-time apartment in New York, buys a sculpture in New York from a North Dakota artist to
14 furnish her apartment, and later sells the sculpture to a friend in New York, the Act requires the
15 payment of a royalty to the North Dakota artist — even if the sculpture, the artist, and the buyer
16 never traveled to, or had any connection with, California.” *Id.*

17 Conversely, in *Rocky Mountain*, the Ninth Circuit held California’s Low Carbon Fuel
18 Standard (“Fuel Standard”), Cal. Code Regs., tit. 17, §§ 95480–90 (2011), did not violate the
19 dormant Commerce Clause’s prohibition on extraterritorial regulation. 730 F.3d at 1078. The
20 California Air Resources Board (“CARB”) implemented the Fuel Standard to lower greenhouse
21 gas (“GHG”) emissions in transportation fuel *consumed in California* by reducing the quantity of
22 GHGs emitted in the production of fuel. *Id.* at 1079–80 (emphasis added). To comply with the
23 Fuel Standard, “a fuel blender must keep the average carbon intensity of its total volume of fuel
24 below the Fuel Standard’s annual limit” and “fuels generate credits or deficits, depending on
25 whether their carbon intensity is higher or lower than the annual cap.” *Id.* at 1080. The Fuel
26 Standard uses a “lifecycle analysis” to account for emissions associated with all aspects of the
27 fuel production process and CARB assigns a cumulative carbon intensity value to an individual
28 fuel lifecycle, known as a “pathway.” *Id.* at 1080–81.

1 The Ninth Circuit concluded the Fuel Standard regulates only the California market, as it
2 stated:

3 [The Fuel Standard] says nothing at all about ethanol produced, sold,
4 and used outside California, it does not require other jurisdictions to
5 adopt reciprocal standards before their ethanol can be sold in
6 California, it makes no effort to ensure the price of ethanol is lower
7 in California than in other states, and *it imposes no civil or criminal
8 penalties on non-compliant transactions completed wholly out of
9 state.*

10 *Id.* at 1101–03 (emphasis added). The court noted California does not control the transportation,
11 farming practices, and land use factors that could encourage producers to adopt less carbon-
12 intensive policies “simply because it factors them into the lifecycle analysis.” *Id.* at 1103. The
13 court also highlighted that the “credits and caps [in the Fuel Standard] apply only to the portfolios
14 of fuel blenders in California and the producers who contract with them.” *Id.* The court
15 concluded that “California properly based its regulation on the harmful properties of fuel” and
16 “[i]t does not control the production or sale of ethanol wholly outside of California.” *Id.* at 1104.

17 Here, with respect to settlement agreements, the language of AB 824 provides that:

18 [A]n agreement resolving or settling, on a final or interim basis, a
19 patent infringement claim, in connection with the sale of a
20 pharmaceutical product, shall be presumed to have anticompetitive
21 effects and shall be a violation of this section if both of the following
22 apply: (A) A nonreference drug filer⁵ receives anything of value from
23 another company asserting patent infringement, including, but not
24 limited to, an exclusive license or a promise that the brand company
25 will not launch an authorized generic version of its brand drug. (B)
26 The nonreference drug filer agrees to limit or forego research,
27 development, manufacturing, marketing, or sales of the nonreference
28 drug filer’s product for any period of time.

29 Cal. Health & Safety Code § 134002(a)(1). With respect to rebutting this presumption, the law
30 provides that:

31 Parties to an agreement are not in violation of paragraph (1) if they
32 can demonstrate by a preponderance of the evidence that either of the
33 following are met: (A) The value received by the nonreference drug
34 filer . . . is a fair and reasonable compensation solely for other goods
35 or services that the nonreference drug filer has promised to provide.
36 (B) The agreement has directly generated procompetitive benefits
37 and the procompetitive benefits of the agreement outweigh the

38 ⁵ The statute defines a “nonreference drug filer” as “[a]n ANDA filer” or “[a] biosimilar
biological product application filer.” Cal. Health & Safety Code § 134000(g).

1 anticompetitive effects of the agreement.

2 *Id.* § 134002(a)(3). The law also contains a civil penalties provision, as follows:

3 Each person that violates or assists in the violation of this section
 4 shall forfeit and pay to the State of California a civil penalty
 5 sufficient to deter violations of this section, as follows: (i) If the
 6 person who violated this section received any value due to that
 7 violation, an amount up to three times the value received by the party
 8 that is reasonably attributable to the violation of this section, or
 9 twenty million dollars (\$20,000,000), whichever is greater. (ii) If the
 10 violator has not received anything of value as described in clause (i),
 11 an amount up to three times the value given to other parties to the
 12 agreement reasonably attributable to the violation of this section, or
 13 twenty million dollars (\$20,000,000), whichever is greater. (iii) For
 14 the purposes of this subdivision, “reasonably attributable to this
 15 violation” shall be determined by California’s share of the market for
 16 the brand drug at issue in the agreement.

17 *Id.* § 134002(e)(1)(A).

18 The State contends that “AB 824 seeks to prevent or reduce anticompetitive
 19 pharmaceutical sales in California, and, thus, applies to agreements to engage in that conduct,”
 20 not “conduct occurring wholly outside California.” (ECF No. 20 at 18–19.) The State asserts “if
 21 manufacturers want to avoid application of AB 824 to agreements they enter into, they can do so
 22 simply by omitting California sales from those covered by the agreement.” (*Id.* at 19.) However,
 23 a review of the relevant sections of the statute reveals no such limitation to only California sales,
 24 unlike the Fuel Standard’s express limitation to fuels consumed in California in *Rocky Mountain*.
 25 730 F.3d at 1079–80. The Court therefore finds persuasive Plaintiff’s hypothetical: “If two
 26 parties settle a patent suit in Delaware on terms that AB 824 deems unlawful, the settling parties
 27 (and every person who merely assists) would be liable for severe penalties under California law.”⁶

28 ⁶ The State contends that “if manufacturers want to avoid application of AB 824 to
 agreements they enter into, they can do so simply by omitting California sales from those covered
 by the agreement,” impliedly arguing that the provisions of AB 824 will not be enforced against
 parties entering into settlement agreements covering pharmaceutical sales outside of California.
 (ECF No. 20 at 19.) The State continually emphasizes in its opposition that AB 824 “does not
 regulate conduct occurring wholly outside California,” “sets the terms of doing business in
 California,” and “governs the prices for which goods are sold in California.” (*Id.* at 18–19.) The
 Court ultimately does not find this argument persuasive as AB 824 on its face does not include
 such a limitation to California sales. 2019 Cal. Legis. Serv. 531; *see also Smallwood v. Allied*
Van Lines, Inc., 660 F.3d 1115, 1121 (9th Cir. 2011) (For purposes of statutory interpretation,
 “[u]nder the ‘plain meaning’ rule, ‘[w]here the language [of a statute] is plain and admits of no

(ECF No. 15-1 at 16 (citing Cal. Health & Safety Code §§ 134002(a), (e)).) The Court finds this hypothetical similar to the hypothetical articulated by the Ninth Circuit in *Sam Francis*. 784 F.3d at 1323–24. As it is written, AB 824 may reach the kind of settlement agreements proposed by Plaintiff — an agreement in which none of the parties, the agreement, or the pharmaceutical sales have any connection with California.

The Court further finds issues with AB 824’s civil penalties provision. One of the factors that weighed against the Ninth Circuit finding an unconstitutional, extraterritorial regulation of commerce in *Rocky Mountain* was that the Fuel Standard did not impose civil or criminal penalties on non-compliant transactions completed wholly out of state. 730 F.3d at 1101–03. That is not the case here. The State characterizes the civil penalties provision in AB 824, which could conceivably impose a \$20 million fine (or more) on a person who received any value for a violation of this section, as “simply alter[ing] the . . . penalties to conduct that was already illegal under California law.” (ECF No. 20 at 18.) The Court finds this argument disingenuous, as AB 824 could be used to levy substantially significant civil penalties on parties that do not have any connection with California. As it is written, the civil penalties provision could hypothetically reach a corporate officer of a Delaware company entering into a settlement agreement with another Delaware company regarding pharmaceutical sales in only Delaware. In light of this provision, the Court cannot reasonably find that AB 824 regulates only the California market.

Based on the foregoing, the Court finds Plaintiff is likely to succeed in showing that AB 824 violates the dormant Commerce Clause. As such, the Court need not and does not address Plaintiff’s alternative claims challenging the legality of AB 824.

D. Immediate and Irreparable Injury

Plaintiff argues “[o]nly an injunction barring enforcement of the statute can prevent its members from suffering further irreparable harm, as “AB 824 has already caused multiple . . . members to lose favorable settlement offers and the value associated with them, and has thus

more than one meaning[,] the duty of interpretation does not arise, and the rules which are to aid doubtful meanings need no discussion.” (citing *Carson Harbor Vill., Ltd. v. Unocal Corp.*, 270 F.3d 863, 878 (9th Cir. 2001) (en banc)). The Court therefore cannot read “California sales” into the statute where it was not written by the State Legislature.

1 caused these members to spend huge sums of money litigating patent cases they otherwise would
2 have settled.” (ECF No. 15-1 at 24.) Plaintiff asserts this economic injury constitutes irreparable
3 injury due to the State’s Eleventh Amendment immunity. (*Id.*) Plaintiff also maintains its
4 members suffer irreparable injury by subjecting them to a law that violates their constitutional
5 rights. (*Id.*)

6 In opposition, the State argues that since AB 824 went into effect, Plaintiff’s members
7 have settled more than 40 patent infringement cases and “there has not been a statistically
8 significant decrease in the number of ANDAs submitted in 2020.” (ECF No. 20 at 27.) The State
9 also notes Plaintiff’s argument of irreparable injury due to subjecting its members to an
10 unconstitutional law is meritless because Plaintiff has not demonstrated a likelihood of success on
11 the merits. (*Id.*)

12 The Court agrees with Plaintiff. The Ninth Circuit has concluded that although monetary
13 harm does not constitute irreparable harm, monetary injury can be irreparable when Eleventh
14 Amendment sovereign immunity prevents a plaintiff from recovering damages in federal court.
15 *Cal. Pharmacists Ass’n v. Maxwell-Jolly*, 563 F.3d 847, 852 (9th Cir. 2009), *vacated on other*
16 *grounds by Douglas v. Indep. Living Ctr. of S. Cal., Inc.*, 565 U.S. 606 (2012). The monetary
17 injury stems from Plaintiff’s members foregoing cost-saving settlement agreements likely deemed
18 unlawful by AB 824 and instead litigating these cases to judgment. Accordingly, the Court is
19 persuaded that Plaintiff’s members will be unable to recover monetary damages against the State
20 even if Plaintiff is successful on the merits of its case.

21 Further, “[I]f the arguments and evidence show that a statutory provision is
22 unconstitutional on its face, an injunction prohibiting its enforcement is ‘proper.’” *Whole*
23 *Women’s Health v. Hellerstedt*, 136 S. Ct. 2292, 2307 (2016) (citing *Citizens United v. Fed.*
24 *Election Comm’n*, 558 U.S. 310, 333 (2010)); *see also Puente Arizona v. Arpaio*, 76 F. Supp.
25 833, 860 (D. Ariz. 2015), *vacated in part on other grounds by Puente Arizona v. Arpaio*, 821 F.3d
26 1098 (9th Cir. 2016). As noted previously, Plaintiff has established a likelihood of success on the
27 merits of its dormant Commerce Clause claim.

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1 Based on the foregoing, the Court finds that Plaintiff has sufficiently shown a likelihood
2 of irreparable harm in the absence of a preliminary injunction.

3 E. Balance of Equities and Public Interest

4 Having found a likelihood of success as to Plaintiff's dormant Commerce Clause claim
5 and a likelihood of irreparable harm absent an injunction, Plaintiff must demonstrate the balance
6 of equities tip in its favor. *See Alliance*, 632 F.3d at 1134–35. A court balancing the equities will
7 look to possible harm that could befall either party. *See CytoSport, Inc. v. Vital Pharm., Inc.*, 617
8 F. Supp. 2d 1051, 1081 (E.D. Cal. 2009), *aff'd*, 348 F. App'x 288 (9th Cir. 2009). Additionally,
9 "[t]he public interest analysis for the issuance of a preliminary injunction requires [the Court] to
10 consider whether there exists [s]ome critical public interest that would be injured by the grant of
11 preliminary relief." *Credit Bureau Connection, Inc. v. Pardini*, 726 F. Supp. 2d 1107, 1123 (E.D.
12 Cal. Jul. 12, 2010) (citing *Indep. Living Ctr. of S. Cal., Inc. v. Maxwell-Jolly*, 572 F.3d 644, 659
13 (9th Cir. 2009)).

14 As noted previously, Plaintiff argues that absent an injunction, its members will suffer
15 economic injury and continue to be subjected to an unconstitutional law. (ECF No. 15-1 at 24.)
16 Plaintiff also asserts that for every day that AB 824 is in effect, the flow of generic and biosimilar
17 medicines into the market slows, resulting in lost savings from such medicines. (*Id.*) Plaintiff
18 maintains AB 824 "has already led to delays in the availability of generic medicines, and it has
19 already driven generic manufacturers to withdraw Paragraph IV ANDAs." (*Id.*)

20 In opposition, the State asserts that "any time a State is enjoined by a court from
21 effectuating statutes enacted by representatives of its people, it suffers a form of irreparable
22 injury." (ECF No. 20 at 28 (citing *Maryland v. King*, 567 U.S. 1301 (2012)).) The State
23 contends that if AB 824 is enjoined, "California will have one less tool at its disposal to combat
24 collusive agreements, and consequently, Californians will be denied affordable drugs and
25 experience increasing insurance premiums." (*Id.*) The State also asserts that it has an interest in
26 ensuring pharmaceuticals are affordable, and AB 824 "is designed to curb the high costs of
27 prescription drugs that affect not only healthcare patients, but also payors such as employers and
28 the Medicare and Medicaid programs." (*Id.*)

1 In light of the irreparable harm to Plaintiff articulated above, the Court finds Plaintiff's
2 arguments with respect to the balance of equities and the public interest persuasive as well.
3 Relative to Plaintiff's injury, the Court agrees with Plaintiff's contention that the harm to the
4 State is relatively *de minimis*, as the State "will still be able to bring enforcement actions under
5 federal antitrust law." (ECF No. 15-1 at 25.) The Court also notes that the State can amend AB
6 824 to ensure that it is compliant with the U.S. Constitution. Finally, the public interest favors a
7 permanent injunction because Plaintiff has established a likelihood of success on its dormant
8 Commerce Clause claim. *See Puente Arizona*, 76 F. Supp. at 861.

9 Based on the foregoing, the Court finds the balance of equities and the public interest
10 element tips sharply in Plaintiff's favor such that an injunction would be proper even if there were
11 only serious questions going to the merits.

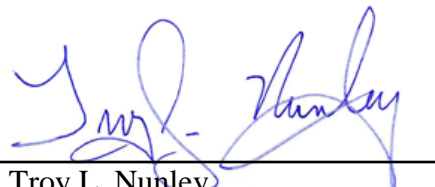
12 IV. CONCLUSION

13 For the foregoing reasons, the Court GRANTS Plaintiff's Motion for Preliminary
14 Injunction to enjoin enforcement of AB 824. (ECF No. 15.)

15 IT IS SO ORDERED.

16 **DATE: December 8, 2021**

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Troy L. Nunley
United States District Judge