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 Defendant Rob Bonta's, in his official capacity as Attorney General of the State of California ("Defendant" or the "State"), Motion to Modify the Preliminary Injunction. (ECF No. 43.) Plaintiff Association for Accessible Medicine ("Plaintiff") filed an opposition. (ECF No. 44.) The State filed a reply. (ECF No. 46.) For the reasons set forth below, the State's motion is GRANTED in part and DENIED in part.

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I. FACTUAL AND PROCEDURAL BACKGROUND

The Court need not recount the background facts of this case as they are set forth fully in its December 9, 2021 Order. (ECF No. 42.) On January 6, 2022, the State filed the instant motion to modify the preliminary injunction ("PI"), requesting the Court modify the injunction to permit AB 824's in-state application and only prohibit the Attorney General from enforcing AB 824 against settlements with no connection to California. (*See* ECF Nos. 43, 43-1.) On January 12, 2022, Plaintiff filed an opposition. (ECF No. 44.) On February 3, 2022, the State filed a reply. (ECF No. 46.)

II. STANDARD OF LAW

"The power of a court of equity to modify a decree of injunctive relief is long-established, broad, and flexible, and when it invokes equity's power to remedy a constitutional violation by an injunction mandating systemic changes to an institution[, it] has the continuing duty and responsibility to address the efficacy and consequences of its order." *Chatman v. Otani*, No. 21-00268 JAO-KJM, 2021 WL 4892311, at *1 (D. Haw. Aug. 18, 2021) (internal quotation marks omitted) (citing *Brown v. Plata*, 563 U.S. 493, 542 (2011)). The burden is on the party seeking to modify the injunction to establish there has been a significant change in facts or law to warrant the modification. *Id.* "This 'requirement presumes that the moving party could have appealed the grant of the injunction but chose not to do so, and thus that a subsequent challenge to the injunctive relief must rest on grounds that could not have been raised before.'" *Id.* (quoting *Alto v. Black*, 738 F.3d 1111, 1120 (9th Cir. 2013)).

Federal Rule of Civil Procedure ("Rule") 54(b) provides in part that "any order or other decision . . . that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities." "Rule 54(b) reflects a district court's 'inherent jurisdiction to modify, alter, or revoke' its own orders before they become final." *S.E.C. v. Schooler*, No. 3:12-cv-2164-GPC-JMA, 2013 WL 5308299, at *2 (E.D. Cal. Sept. 19, 2013) (quoting *United States v. Martin*, 226 F.3d 1042, 1049 (9th Cir. 2008)). Courts will grant a motion to modify a preliminary injunction

if: "(1) the movant presents the court with newly discovered evidence; (2) the court committed clear error or the initial decision was manifestly unjust; or (3) there is an intervening change in controlling law." *Id.*; *see also Ubiquiti Networks, Inc. v. Kozumi USA Corp.*, No. C 12-2582 CW, 2012 WL 5373377, at *1 (N.D. Cal. Oct. 30, 2012); *Commodity Futures Trading Comm'n v. Bame*, No. CV 08-05593 RGK (PLAx), 2009 WL 10675779, at *2 (C.D. Cal. Jul. 1, 2009).

III. ANALYSIS

The State requests the Court modify the injunction to allow for AB 824's in-state application and provides two specific examples where AB 824 may be constitutionally applied consistent with the Court's December 9, 2021 Order with respect to in-state sales and in-state settlements. (ECF No. 43-1 at 8–11.) The State contends the Court should modify the injunction to "enjoin only the unconstitutional applications of a statute while leaving the other applications in force." (*Id.* at 7–8 (quoting *Ayotte v. Planned Parenthood of N. New England*, 546 U.S. 320, 328–39 (2006)).) The State also requests the Court clarify and confirm the injunction is only applicable to Plaintiff, arguing that "a plaintiff in an as-applied challenge may not obtain injunctive relief for third parties." (*Id.* at 11.) The Court will consider each of the State's examples in turn and then address the request for clarification.

A. In-State Sales

The State requests the Court allow California to continue to enforce AB 824 whenever a settlement agreement is made in connection with in-state pharmaceutical sales "if that agreement artificially distorts the pharmaceutical market in California." (ECF No. 43-1 at 8–10.) The State argues this is consistent with the canon of statutory interpretation that California statutes are presumed to only apply in-state.[1] (*Id.* at 8–9.) The State also argues this is consistent with the Ninth Circuit's dormant Commerce Clause precedent in *Chinatown Neighborhood Ass'n v.*

[1] The Court agrees with the State that it must apply California's canons of statutory interpretation when interpreting California law (*see* ECF No. 43-1 at 9 n.3 (citing *In re First T.D. & Invs., Inc.*, 253 F.3d 520, 527 (9th Cir. 2001))), but the case Plaintiff cites for the proposition that there is a presumption against extraterritorial application of California statutes deals with whether "California's antitrust and unfair competition laws can reach extraterritorial conduct causing injury in California" (*id.* (citing *RLH Indus., Inc. v. SBC Commc'ns, Inc.*, 133 Cal. App. 4th 1277, 1292 (2005)), which is different from the issue here.

Harris, 794 F.3d 1136, 1145–46 (9th Cir. 2015), in which the court upheld a dormant Commerce Clause challenge to California law banning the sale of shark fins by presuming "the law would only apply to sales or possession 'in California.'" (*Id.* at 10.)

In opposition, Plaintiff asserts the State's request would "render the injunction (and the dormant Commerce Clause) a practical nullity" because "***every*** pharmaceutical patent settlement [agreement] is 'a settlement agreement made in connection with the sale of pharmaceutical products in California' because 'all FDA-approved generics are sold in California, the largest market in the Nation.'" (ECF No. 44 at 2 (emphasis in original) (quoting ECF No. 26 at 5 n.5).) Plaintiff rejects the State's argument about being able to regulate settlement agreements if they "artificially distort the pharmaceutical market in California," arguing that "the dormant Commerce Clause prohibits states from 'regulating commerce occurring wholly outside [their] borders' — including, for example, a settlement resolving patent litigation out[-]of[-]state — ***even if the out-of-state commerce 'has effects within the State***.'" (*Id.* at 2 (emphasis in original) (quoting *Healy v. Beer Inst.*, 491 U.S. 324, 332 (1989)).)

In reply, the State argues AB 824 "may permissibly extend to extraterritorial economic activity so long as it is tied to in-state transactions because the relevant conduct does not occur *wholly* outside the state's borders." (ECF No. 46 at 2–3 (emphasis in original).) The State maintains the agreements "obligate generic producers not to compete *in the California market*." (*Id.* at 3 (emphasis in original).) The State argues the Court should leave standing the portion of AB 824 that regulates the state's own market and "permit AB 824" to be applied to settlements made in connection with California sales because such conduct would not occur wholly beyond California's borders." (*Id.* at 3–4.)

In *Chinatown*, the plaintiffs argued, among other things, that California's law making it "unlawful for any person to possess, sell, offer for sale, trade, or distribute a shark fin" (the "Shark Fin Law") violated the dormant Commerce Clause. 794 F.3d at 1139. The plaintiffs argued "the Shark Fin Law is per se invalid under the Commerce Clause because it regulates extraterritorially by curbing commerce in shark fins between California and out-of-state destinations, and by preventing the flow of shark fins through California from one destination to

another." *Id.* at 1145. The court found that the extraterritorial reach of the Shark Fin Law did not render it "per se invalid" because "a state may regulate commercial relationships in which at least one party is located in California" and "even when the state law has significant extraterritorial effects, it passes Commerce Clause muster when, as here, those effects result from the regulation of in-state conduct." *Id.* at 1145–46 (internal citations and quotation marks omitted). Most importantly, the Ninth Circuit concluded that "[t]he Shark Fin Law does not fix prices in other states, require those states to adopt California standards, or attempt to regulate transactions conducted wholly out of state . . . ." *Id.* at 1146.

While the Court acknowledges the Shark Fin Law did not contain an express limitation on the applicability of the statute to California, the Court nevertheless finds *Chinatown* is sufficiently distinguishable from the present case. As just stated, the Shark Fin Law did "not attempt to regulate transactions conducted wholly out of state." 794 F.3d at 1146. There was no out-of-state resident plaintiff who alleged the Shark Fin Law prevented her from being able to purchase shark fins in her home state nor were there any allegations from the plaintiffs that the Shark Fin Law regulated actions taking place entirely outside of California with parties who have no connection to California. Additionally, whether the Shark Fin Law applied to the possession, sale, offer for sale, trade, or distribution of shark fin *in California* was not in dispute. The Ninth Circuit had no need to address this issue as the plaintiffs seemed to concede the Shark Fin Law only applied in California. Conversely, Plaintiff argues AB 824 — because the language of the statute 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. As the Court stated in its December 9, 2021 Order, "[a]s 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." (ECF No. 42 at 15.) Additionally, Plaintiff submitted a declaration from one of its members that avers 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.)

The State is correct that the Supreme Court has concluded that courts should "enjoin only the unconstitutional applications of a statute while leaving other applications in force." *Ayotte*, 546 U.S. at 329. The Supreme Court has set forth three guiding principles to in its approach as follows:

> First, we try not to nullify more of a legislature's work than is necessary, for we know that [a] ruling of unconstitutionality frustrates the intent of the elected representatives of the people . . . Second, mindful that our constitutional mandate and institutional competence are limited, we restrain ourselves from rewrit[ing] state law to conform it to constitutional requirements even as we strive to salvage it . . . Third, the touchstone for any decision about remedy is legislative intent, for a court cannot use its remedial powers to circumvent the intent of the legislature.

Id. at 329–30 (internal citations and quotation marks omitted).

The State's request is essentially for the Court to add "in California" to the statute and construe it as follows: ". . . . an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product [in California], shall be presumed to have anticompetitive effects and shall be a violation of this section if both of the following apply . . . ." Cal. Health & Safety Code § 134002(a)(1). If the Court were to do this, it envisions a scenario in which the underlying dormant Commerce Clause problem (and Plaintiff's hypothetical from its previous briefing) still remains. Plaintiff's hypothetical was as follows: "If two parties settle a patent suit in Delaware on terms that AB 824 deems unlawful, the settling parties (and every person who merely assists) would be liable for severe penalties under California law." (ECF No. 15-1 at 16.) Plaintiff underscores that "every pharmaceutical patent settlement is 'a settlement agreement made in connection with the sale of pharmaceutical products in California,' because 'all FDA-approved generics are sold in California, the largest market in the Nation.'" (ECF No. 44 at 2 (citing ECF No. 26 at 5 n.5).) Accordingly, it is possible the hypothetical Plaintiff presents could be construed to be "a settlement agreement made in connection with the sale of pharmaceutical products in California." The dormant Commerce Clause "precludes the application of a state statute to commerce that takes place

wholly outside of the State's borders, whether or not the commerce has effects within the State" and "[t]he critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State." *Healy*, 491 U.S. at 336 (citing *Edgar v. MITE Corp.*, 457 U.S. 624, 642–43 (1982) (plurality opinion); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579, 581–83 (1986)). Therefore, allowing the State to enforce such an agreement under AB 824 would run afoul of the dormant Commerce Clause.

Further, the Court finds that in order to make the "in-state sales" compliant with the dormant Commerce Clause, it would entail "rewrit[ing] state law to conform it to constitutional requirements," which inherently is beyond the Court's "constitutional mandate." *See Ayotte*, 546 U.S. at 329–30. Accordingly, the Court DENIES the State's request to allow California to continue to enforce AB 824 whenever a settlement agreement is made in connection with in-state pharmaceutical sales.

B. In-State Settlements

The State next requests the Court allow California to enforce AB 824 with respect to settlement agreements negotiated, completed, or entered into within California's borders. (ECF No. 43-1 at 10–11.) The State asserts Plaintiff never argued this application would run afoul of the dormant Commerce Clause. (*Id.* at 10.) In opposition, Plaintiff asserts it moved to enjoin AB 824 on multiple grounds and therefore opposes limiting the injunction on that basis. (ECF No. 44 at 5.) However, Plaintiff notes that "to the extent the Court intends to narrow the injunction to be tailored to remedy the dormant Commerce Clause violation only, the injunction must conform to the relevant Supreme Court and Ninth Circuit precedent . . . *i.e.*, it must prevent the [Attorney General] (and his agents, etc.) from enforcing AB 824 with respect to any pharmaceutical patent settlement entered out of state, even if that settlement has effects in California or vis-à-vis in-state sales." (*Id.*) In reply, the State notes Plaintiff does not dispute this argument but "the mere fact that [Plaintiff] has brought other, unresolved claims, is no basis to maintain the injunction on the current record . . . ." (ECF No. 46 at 5.) The State contends "the injunction must be narrowed to fit [Plaintiff's] actual Commerce Clause challenge," as "an overbroad injunction is an abuse of discretion." (*Id.*)

The Court agrees that Plaintiff does not contest whether the State can enforce AB 824 with respect to settlement agreements negotiated, completed, or entered into within California's borders. Further, such agreements are compliant with the dormant Commerce Clause because they regulate conduct occurring wholly within California's borders. *See Healy*, 491 U.S. at 336. Accordingly, the Court GRANTS the State's request to allow California to continue to enforce AB 824 with respect to settlement agreements negotiated, completed, or entered into within California's borders.

The Court has also evaluated the additional grounds upon which Plaintiff moved to enjoin AB 824 in its original motion (ECF Nos. 15, 15-1) and finds Plaintiff does not establish a likelihood of success on the merits of any of its remaining claims such that enjoining enforcement of AB 824 with respect to settlement agreements negotiated, completed, or entered into within California's borders would be proper. Apart from its dormant Commerce Clause argument, Plaintiff contends AB 824: is preempted by federal patent law, the delicate balance between the competing interests of patent protections and antitrust law struck by the Supreme Court in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), and the Biologics Price Competition and Innovation Act ("BPCIA"); violates the constitutional prohibition on excessive fines under the Eighth Amendment; and violates due process in that it creates a burden-shift with no meaningful opportunity to rebut the presumption applied. (*See* ECF Nos. 15, 15-1.) Plaintiff makes largely the same legal arguments as it did in its previous motion for preliminary injunction. (*See* ECF No. 29; No. 2:19-cv-02281-TLN-DB.) The Court will evaluate each argument in turn.

i. Preemption

Plaintiff argues AB 824 is directly preempted by two provisions of the Patent Act (35 U.S.C. §§ 261, 282(a)) and BPCIA, conflicts with the objectives of federal patent law (the Hatch-Waxman Act), and is inconsistent with the delicate balance struck between antitrust and patent law as discussed by the Supreme Court in *Actavis*. With respect to the Hatch-Waxman Act and *Actavis*, the Court finds that Plaintiff raises the same arguments that it already addressed in its prior Order denying Plaintiff's motion for preliminary injunction. (ECF No. 29 at 13–16, No. 2:19-cv-02281-TLN-DB.) The Court will therefore only address Plaintiff's arguments on direct

preemption by the Patent Act and BPCIA.

a) Patent Act

Plaintiff first argues AB 824 conflicts with 35 U.S.C. § 261, which gives patent holders the right to grant exclusive licenses. (ECF No. 15-1 at 16.) Plaintiff contends AB 824 "expressly defines a reverse payment ('anything of value')" to include an exclusive license. (*Id.* at 16–17 (citing Cal. Health & Safety Code § 134002(a)(1)(A)).) Plaintiff next argues AB 824 conflicts with 35 U.S.C. § 282(a), which provides that patents shall be presumed valid and enforceable. (*Id.* at 17.) Plaintiff notes AB 824 "prohibits factfinders from presuming that 'any patent is enforceable,' . . . [and] thus directly diminishes the value of a federally conferred patent[.]" (*Id.* (citing Cal. Health & Safety Code § 134002(b)(2)).)

In opposition, the State asserts "AB 824 does not reach exclusive licenses unless the license is given to induce a rival to agree not to compete . . . [which] is not given by or protected by patent law." (ECF No. 20 at 21 (citing *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 407 (3d Cir. 2015)).) The State also maintains "AB 824 does not alter the presumption of validity, [but rather] prohibits factfinders from presuming that any patent is enforceable." (*Id.* at 21–22.) The State notes that 35 U.S.C. § 282(a) states that a patent will be presumed valid, not enforceable — the distinction is that the former "relates to whether the patent conforms with certain statutory requirements," while the latter "relates to whether the patent was procured by fraud or wrongdoing." (*Id.* at 22.)

While the Court in its prior Order in the related case stated that Plaintiff had not pointed to any provision of the Patent Act that conflicts with AB 824, it also concluded that AB 824 does not conflict with federal patent law because it does not require determination of the validity of a patent and does not create patent-like protections. (ECF No. 29 at 12–13; No. 2:19-cv-02281-TLN-DB.) Accordingly, the Court similarly finds here that AB 824 does not conflict with the specific provisions of the Patent Act — 35 U.S.C. §§ 261, 282(a) — to which Plaintiff now cites in its motion.

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b) BPCIA

Plaintiff argues "AB 824 is also preempted to the extent it purports to apply to patent settlements involving biologics and biosimilars under the BPCIA," as its "patent litigation provisions create a comprehensive procedural roadmap and specific consequences from departing from it" and "'intentionally' limit injunctive relief to one circumstance and provide no damages remedy at all." (ECF No. 15-1 at 20 (citing *Sandoz Inc. v. Amgen Inc.* (*Amgen I*), 137 S. Ct. 1664, 1674–75 (2017)).) Plaintiff notes the Federal Circuit has held "state regulation of 'biosimilar patent litigation' is categorically off-limits, as 'the federal government has fully occupied this field.'" (*Id.* (citing *Amgen Inc. v. Sandoz Inc.* (*Amgen II*), 877 F.3d 1315, 1328–30 (Fed. Cir. 2017).)

In opposition, the State maintains the *Amgen II* case concludes that the BPCIA "preempts state law remedies for a BPCIA applicant's failure to comply with the BPCIA notice provision" and is therefore not "a blanket ruling that states cannot regulate drug sales within the state." (ECF No. 20 at 24 (citing *Amgen II*, 877 F.3d at 1320).)

There are three forms of federal preemption: (1) explicit preemption of state law by Congress; (2) field preemption, where the "federal scheme may occupy a given field and thus preempt state law in that field;" and (3) conflict preemption, where "compliance with both state and federal law is impossible" and "the conflicting state law is preempted." *Univ. of Colo. Found., Inc. v. Am. Cyanamid Co.*, 342 F.3d 1298, 1305 (Fed. Cir. 2003). "Conflict preemption occurs 'where it is impossible for a private party to comply with both state and federal requirement, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Amgen II*, 877 F.3d at 1326.

The BPCIA "established an abbreviated pathway for producers of biologic products deemed sufficiently similar to products already on the market ('biosimilars') to receive [FDA] license approval." *Amgen Inc. v. Sandoz Inc.* (*Amgen III*), No. 14-cv-04741-RS, 2015 WL 1264756, at *1 (N.D. Cal. Mar. 19, 2015), *vacated in part on other grounds*, 794 F.3d 1347 (9th Cir. 2015). The BCPIA "establishes processes both for obtaining FDA approval of biosimilars and for resolving patent disputes between manufacturers of licensed biologics and manufacturers

of biosimilars." *Amgen I*, 137 S. Ct. at 1675. The Supreme Court "has described the BCPIA as possessing a 'carefully crafted and detailed enforcement scheme' and stated that this scheme 'provides strong evidence that Congress did *not* intend to authorize other remedies that it simply forgot to incorporate expressly." *Amgen II*, 877 F.3d at 1328 (emphasis in original) (quoting *Amgen I*, 137 S. Ct. at 1675). The State is correct that the Federal Circuit has held that because the BCPIA "provides the exclusive federal remedy for failure to comply with [its provisions], federal law does not permit injunctive relief or damages for such failure," and allowing the State "to impose its own penalties for the [alleged violation of federal law] here would conflict with the careful framework Congress adopted." *Id.* (quoting *Arizona v. United States*, 567 U.S. 387, 402 (2012)). In a similar vein, the Federal Circuit also held that where "state law claims 'clash' with the BPCIA, . . . the differences in remedies between the federal scheme and state law claims support concluding that those claims are preempted." *Id.* at 1329.

Here, AB 824 does not contain any provisions regarding state law remedies for failure to comply with the provisions of the BPCIA. As has been noted, AB 824 creates a presumption that "reverse payment" settlement agreements regarding patent infringement claims between brand-name and generic pharmaceutical companies are anti-competitive and unlawful. Cal. Health & Safety Code § 134002(a)(1). It also levies a civil penalty against any individual who assists in the violation of the section of three times the value received by the individual due to the violation or $20 million, whichever the greater. *Id.* § 134002(e)(1)(A). In light of these provisions, it is possible for an individual to comply both with the provisions of the BPCIA as well as AB 824. Additionally, to the extent that the BPCIA sets forth a scheme for resolution of patent infringement claims, AB 824 does not conflict with the BPCIA because AB 824 does not require determination of the validity of a patent nor does it create patent-like protections. Accordingly, the Court finds that the BPCIA does not conflict with the provisions of AB 824.

Based on the foregoing, the Court finds that there is not a likelihood of success as to the merits of Plaintiff's preemption claim.

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ii. Excessive Fines

Plaintiff argues its Excessive Fines claim is ripe and likely to succeed on the merits. (ECF No. 15-1 at 21–22.) Plaintiff contends "there is no set of circumstances under which the minimum penalty AB 824 authorizes could constitutionally be applied to a person who has not received anything of value as a result of her role." (*Id.* at 22 (emphasis omitted).) Plaintiff maintains the Court should not wait for the State to bring an enforcement action before deciding this claim on the merits because the abstention doctrine in *Younger v. Harris*, 401 U.S. 37 (1971), would preclude "an individual who allegedly assisted in a violation from seeking a federal injunction precluding AB 824's penalty provisions from being applied to him or her." (*Id.*) In opposition, the State contends Plaintiff's claim is not ripe and fails on its merits. (ECF No. 20 at 24–26.) With respect to ripeness specifically, the State asserts Plaintiff has not offered evidence that an individual intends to violate AB 824 nor that the State has communicated a threat of levying a $20 million fine. (*Id.* at 25.) The State notes "the prudential inquiry also points to a finding that 'the claim is unripe as it requires factual development.'" (*Id.* (citing ECF No. 29 at 19; No. 2:19-cv-02281-TLN-DB).)

In evaluating a claim under the Excessive Fines Clause, "the standard of gross disproportionality" requires a court to "compare the amount of the forfeiture to the gravity of the [ ] offense. If the amount of the forfeiture is grossly disproportionate to the gravity of the defendant's offense, it is unconstitutional." *United States v. Bajakajian*, 524 U.S. 321, 336–37 (1998). In the Ninth Circuit, this typically requires courts to consider four factors: (1) the nature and extent of the violation; (2) whether the violation was related to other illegal activities; (3) other penalties that may be imposed for the violation; and (4) the extent of the harm caused. *See United States v. $132,245.00 in U.S. Currency*, 764 F.3d 1055, 1058 (9th Cir. 2014).

As the Court noted in its prior Order (*see* ECF No. 29 at 18–20; No. 2:19-cv-02281-TLN-DB), each of these four factors — perhaps with the exception of the third — are all but impossible to assess in the abstract, highlighting the difficulty of a pre-enforcement attack based on the Excessive Fines Clause. As one district court has noted in a case where no penalty had been imposed, as is the case here, "[a] fact-specific determination of excessiveness is impossible

where any wrongful conduct is hypothetical." *Crawford v. U.S. Dep't of the Treasury*, No. 3:15-CV-250, 2015 WL 5697552, at *14–15 (S.D. Ohio Sept. 29, 2015). Additionally, without examining the factual underpinnings of an actual violation, the Court cannot speculate as to the nature and extent of the violation, whether the violation is related to other illegal activities, and the extent of the harm caused. *See $132,245.00*, 464 F.3d at 1058. Without the factual underpinnings by which to assess a violation, it is impossible to know whether the upper threshold imposed by AB 824 or the $20 million fine as applied to individuals is excessive. The Court reiterates that it is not willing at this point to find the upper threshold of AB 824's penalty provision grossly disproportionate to the gravity of every conceivable violation of the statute. Accordingly, the Court agrees with the State that Plaintiff's Excessive Fines claim is not ripe for adjudication.

iii. Due Process

With respect to Plaintiff's Due Process claim, the Court finds that Plaintiff raises the same arguments that the Court already addressed in its prior Order denying its motion for preliminary injunction. (ECF No. 29 at 13–16, No. 2:19-cv-02281-TLN-DB.) Accordingly, the Court declines to address the same arguments again.

The Court finds its conclusions regarding immediate and irreparable injury, the balance of equities, and the public interest have not changed since its December 9, 2021 Order. (*See* ECF No. 42.) Accordingly, the Court declines to enjoin enforcement of AB 824 with respect to settlement agreements negotiated, completed, or entered into within California's borders on any of the foregoing bases.

C. Applicability of the Preliminary Injunction

As a preliminary matter, the Court agrees with the State that Plaintiff's challenge is as-applied rather than facial, as it alleges in the Complaint that "AB 824 violates the Commerce Clause as applied to settlement agreements that were not negotiated, completed or entered in California." (ECF No. 43-1 at 6 (citing ECF No. 1 ¶ 85).)

As stated previously, the State requests the Court clarify and confirm the injunction is only applicable to Plaintiff, arguing that Plaintiff "only moved to enjoin enforcement of AB 824

against '[Plaintiff], its member companies, or their agents and licensees'" and "a plaintiff in an as-applied challenge may not obtain injunctive relief for third parties." (*Id.* at 11 (citing ECF No. 15).) In opposition, Plaintiff asserts that "[a]t a minimum . . . the Court's injunction must protect [Plaintiff], its members, and their agents and licensees, as well as any person or entity whose participation in the negotiation of a covered settlement agreement is necessary." (ECF No. 44 at 4.) In reply, the State clarifies that it "does not object to the injunction to the extent it covers both [Plaintiff] as an organization and its member entities," but "[b]eyond that, the injunction should not extend any further." (ECF No. 46 at 6.) The State also notes Plaintiff "has provided no analysis or reason why its agents and licensees must be included in any injunction order." (*Id.*)

Because the challenge is as-applied, the Court agrees the injunction applies only to Plaintiff. Both parties apparently agree that the injunction should apply to Plaintiff's member entities as well. As the State itself notes, Plaintiff specifically argued in its motion for preliminary injunction to bar the State and the Attorney General from implementing or enforcing AB 824 against Plaintiff, "its member companies, or their agents and licensees." (ECF No. 15 at 1.) The State did not specifically oppose this request or make any argument about the applicability of an injunction in its original opposition (*see* ECF No. 20), nor does it provide adequate case law[2] to support its contention that the injunction should not apply to Plaintiff's or its member entities' agents and licensees now (*see* ECF Nos. 43-1, 46). Accordingly, the Court clarifies that the injunction applies with respect to Plaintiff, its member entities, or their agents and licensees.

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[2] The State provides only a single case in its motion for the proposition that "a plaintiff in an as-applied challenge may not obtain injunctive relief for third parties." (ECF No. 43-1 at 11 (citing *Free Speech Coalition Inc. v. Attorney General United States*, 974 F.3d 408, 430 (3d Cir. 2020)).) In this case, the Third Circuit vacated the district court's order entering a nationwide injunction as broader than necessary and remanded for entry of relief limited to the successful as-applied plaintiffs. *Free Speech Coalition, Inc.*, 974 F.3d at 430–31. The State and Plaintiff already agree the injunction should apply to Plaintiff and its member entities, and *Free Speech Coalition, Inc.* provides no support for the State's argument with respect to agents and licensees.

IV. CONCLUSION

For the foregoing reasons, the Court hereby GRANTS in part and DENIES in part the State's Motion to Modify the Preliminary Injunction. (ECF No. 43.) The Court's December 9, 2021 Order granting Plaintiff's motion for preliminary injunction to enjoin enforcement of AB 824 is modified to allow the State to enforce the provisions of AB 824 with respect to settlement agreements negotiated, completed, or entered into within California's borders. Additionally, the Court clarifies that the injunction bars the Attorney General of the State of California, as well as the Attorney General's officers, agents, employees, attorneys, and all persons in active concert or participation with them from implementing or enforcing AB 824 against Plaintiff, its member entities, or their agents and licensees, with the exception of settlement agreements negotiated, completed, or entered into within California's borders.

IT IS SO ORDERED.

DATED: February 14, 2022

Troy L. Nunley
United States District Judge