Ass'n for Accessible Meds. v. Becerra

Decided Dec 31, 2019

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

12-31-2019

ASSOCIATION FOR ACCESSIBLE MEDICINES, Plaintiff, v. XAVIER BECERRA, in his official capacity as Attorney General of the State of California, Defendant.

Troy L. Nunley United States District Judge

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. /// *2

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I. FACTUAL AND PROCEDURAL BACKGROUND [1]

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

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.

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

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

Settlements of the resulting lawsuits sometimes include reverse payments in which the plaintiff, the brand-
3 name drug company, pays the defendant, the infringing generic drug *3 company, a sum of money for the promise that the generic drug company will keeps its drug off the market for an agreed-upon length of time.

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

AB 824 imposes a presumption that a settlement agreement involving a brand-name company compensating the generic for keeping its drug off the market is anticompetitive under California Antitrust Law. 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 is greater.

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

II. STANDARD

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. Natural 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
4 preserve the relative positions of the parties until *4 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 plaintiff also shows that there is a likelihood of irreparable injury and that the injunction is in the public interest." *Id*. Simply put, a plaintiff must demonstrate, "that [if] serious questions going to the merits were raised [then] the balance of hardships [must] tip[ ] sharply in the plaintiff's favor," in order to succeed in a request for preliminary injunction. *Id*. at 1134-35 (emphasis added).

III. STANDING

Neither party has raised any issues with respect to standing. Nevertheless, "federal courts are required *sua sponte* to examine jurisdictional issues such as standing." *Chapman v. Pier 1 Imports (U.S.) Inc.*, 631 F.3d 939, 954 (9th Cir. 2011) (quoting *Bernhardt v. Cty. of L.A.*, 279 F.3d 862, 868 (9th Cir. 2002)). And "[t]he existence of Article III standing is not subject to waiver." *Chapman*, 631 F.3d at 954. To establish Article III standing, a plaintiff must have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). *5

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

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

IV. REQUEST FOR JUDICIAL NOTICE

At the outset, Defendant requests the Court take judicial notice of five documents pursuant to Federal Rule of Evidence 201: (1) Assembly Committee on Health AB 824 Bill Analysis (March 26, 2019), attached to Defendant's Request for Judicial Notice ("RJN," ECF No. 24-1) as Exhibit A; (2) Assembly Floor Analysis of AB 824 (September 4, 2019), attached to RJN as Exhibit B; (3) Letters of Support for AB 824, attached to RJN as Exhibit C; (4) Table 8: *6 Total All Payers State Estimates by State of Residence (1991-2014) — Drugs and Other Non-durable Products (Millions of Dollars), attached to RJN as Exhibit D; and (5) *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, FTC Staff Study (Jan. 2010), attached to RJN as Exhibit E. The State contends judicial notice of Exhibits A, B, and C is appropriate because they are documents that are part of the legislative history of AB 824. The State asserts Exhibits D and E are appropriate for judicial notice because the documents were "administered by or filed with an administrative agency that is not subject to reasonable dispute and is 'capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.'" (ECF No. 24-1 at 2, *quoting* Fed. R. Evid. 201.) Plaintiff does not oppose the State's request, and the Court finds all five documents are appropriate for judicial notice.

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

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

V. PRELIMINARY INJUNCTION ANALYSIS

Plaintiff's Complaint asserts five causes of action, the first four of which encompass the present request for preliminary injunction. As explained below, and primarily due to the nature of Plaintiff's pre-enforcement attack on AB 824, the Court finds Plaintiff has failed to establish a *7 likelihood of success on the merits of its claims, nor has it raised serious questions going to those merits. Moreover, the Court finds that absent a constitutional violation Plaintiff has failed to establish an irreparable harm that is both likely and — at this time — imminent. And lastly, even if the Court were to find serious questions going to the merits of Plaintiff's claims, the question of balance of harms and public interest are too speculative at this point for the Court to find that either factor favors Plaintiff, sharply or otherwise.

A. Likelihood of Success on the Merits

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

1. Dormant Commerce Clause

In its moving papers, Plaintiff indicates 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. Interpreting this as a facial attack on AB 824, the State argues that because AB 824 can conceivably be applied to settlement agreements contained within California, it has at least one constitutional application and so Plaintiff's facial attack fails.

Indeed, a facial challenge is "the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid. The fact that [an] Act might operate unconstitutionally under some conceivable set of circumstances is insufficient to render it wholly invalid, since we have not recognized an 'overbreadth' doctrine outside the limited context of the First Amendment." *United States v. Salerno*, 481 U.S. 739, 745 (1987). Facial challenges are disfavored because they often require the court to make constitutional determinations based on hypothetical situations. *Washington State Grange v. Washington State Republican Party*, 552 U.S. 442, 449-51 (2008) ("Claims of
8 *8 facial invalidity often rest on speculation. As a consequence, they raise the risk of premature interpretation of statutes on the basis of factually barebones records." (internal citation omitted)). Here, Plaintiff poses the hypothetical situation of non-California entities entering into a settlement agreement outside of California, and then asks the Court to assume that California would seek to enforce AB 824 against these hypothetical parties. But invalidating or even preliminarily enjoining the law on this basis would force the Court to not only assume the Attorney General will apply the law unconstitutionally, but also to make a constitutional determination before it is necessary to do so. *Washington State Grange v. Washington State Republican Party*, 552 U.S. 442, 449-51 (2008) ("Facial challenges also run contrary to the fundamental principle of judicial restraint that courts should neither anticipate a question of constitutional law in advance of the necessity of deciding it nor formulate a rule of constitutional law broader than is required by the precise facts to which it is to be applied." (internal quotes and citations omitted)). Such a facial attack therefore fails where, as here, a set of circumstances exists under which AB 824 will be valid.

Plaintiff seems to concede this point, clarifying its position in its reply brief and in oral argument that it is not raising a facial attack against AB 824, but an as-applied attack. (ECF No. 27 at 7.) An as applied challenge looks at a specific plaintiff and set of circumstances and determines if the law is constitutional as applied to that set of circumstances. *Wal-Mart Stores, Inc. v. City of Turlock*, 483 F. Supp. 2d 987, 996-97 (E.D. Cal. 2006) (citing 16 C.J.S. Constitutional Law § 187) ("When faced with a claim that application of a statute renders it unconstitutional, a court must analyze the statute as applied to the particular case, i.e., how it operates in practice against the particular litigant and under the facts of the instant case, not hypothetical facts in other situations"). In other words, Plaintiff claims AB 824 "*as applied* to settlement agreements that were not negotiated, completed, or entered in California," violates the Dormant Commerce Clause. (ECF No. 27 at 7.) Indeed, if the Attorney General were to enforce the terms of AB 824 against two out of state parties that entered into a settlement agreement outside of California, having nothing to do with California, such conduct would likely violate the Dormant Commerce Clause. In this case, however, AB 824 has yet to take effect. As a
9 result, the *9 Court cannot consider the law *as it has been applied* to a particular agreement or party. Rather, Plaintiff raises a "paradigmatic as-applied challenge" to AB 824, urging the Court to find that "the application of the statute to a specific factual circumstance" is in violation of the Dormant Commerce Clause. (*Id.* (citing *Hoye v. City of Oakland*, 653 F.3d 835, 857 (9th Cir. 2011)).) Plaintiff asserts the fact that AB 824 hasn't been enforced yet is not detrimental to its challenge, citing case law in support of its position that a pre-enforcement as-applied challenge is ripe "so long as [it] present[s] a 'discrete and well-defined' application of the challenged law that is 'likely to occur.'" (*Id.* (citing *Gonzales v. Carhart*, 550 U.S. 124, 167 (2007)).)

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

Whether Plaintiff's Dormant Commerce Clause claim as asserted is likely to succeed depends first on whether that claim is ripe. While allowing pre-enforcement, as-applied challenges, *Gonzalez* does not allow for Plaintiff's broad request. In *Gonzalez*, the Supreme Court denied a request to find a partial-birth abortion ban facially unconstitutional. Instead, it concluded that an as-applied challenge was the "proper means to consider exceptions" to the law because in such an as-applied challenge "it can be shown that in discrete and well-defined instances a particular condition has or is likely to occur in which the prohibited act must be used." *Id*. at 167. In the first instance, it is not clear to the Court that *Gonzalez*' standard applies outside of the narrow context of abortion law. Moreover, *Gonzalez* says nothing about the specificity needed to bring a pre-enforcement as-applied challenge but instead reinforces the general proposition that the court should not reach
10 findings of unconstitutionality based on hypotheticals.[2] *10

[2] Neither does *Hoye v. City of Oakland*, 653 F.3d 835 (9th Cir. 2011) stand for the broad proposition that a party can successfully bring an as-applied pre-enforcement challenge to a statute under all circumstances. Rather, aside from articulating that a paradigmatic as-applied approach can be appropriate at least in the context of First Amendment jurisprudence, *Hoye* offers 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.

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

Even so, applying either *Clarks* three-pronged test or the more general rule as stated in *Gonzalez* to the instant case, Plaintiff has not established a likelihood of success on the merits of its pre-enforcement as-applied challenge because it has not established that the issue is ripe for review. Specifically, Plaintiff has not sufficiently shown that AB 824 is likely to be enforced in an unconstitutional manner, nor has Plaintiff stated neither a plan to violate the law or a specific threat that the law will be enforced in the manner they fear.
11 Plaintiff relies heavily on the *11 declarations it submitted in support of its motion for preliminary injunction.

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

Because the Court finds Plaintiff's pre-enforcement as-applied claim under the Dormant Commerce Clause is not ripe for review, the Court finds Plaintiff has not established a likelihood of success on the merits of its claim, nor has Plaintiff raised serious questions going to the merits, and so a preliminary injunction shall not
12 issue on these grounds at this time.[3] Even if Plaintiff *12 had raised serious questions as to the merits of its Dormant Commerce Clause claim, the balance of hardships does not tip significantly in Plaintiff's favor, as discussed below, such that a preliminary injunction should be granted.

[3] Plaintiff's pre-enforcement as-applied challenge is also problematic because it may be construed as an attempt to extend a facial overbreadth challenge outside the First Amendment context. In theory, Plaintiff claims that the language of the law in question is overbroad because it may allow the government to enforce it unconstitutionally. *See*, *e.g.*, *Sabri v. U.S.*, 541 U.S. 600, 609 (2004) ("It would have been correspondingly clear that if Sabri was making any 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 legislature would have to include language specifically limiting its application to within California. That simply cannot be the case, and Plaintiff cites to no authority indicating 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.

2. Preemption

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

Plaintiff indeed has not pointed to any provision of the Patent Act that conflicts with AB 824 except to assert in oral argument that federal patent law is entitled to field preemption and states cannot create their own patent-like protections. While this assertion is correct, it does not settle the question of preemption presented to this Court. "[S]tate law is preempted when it enters 'a field of regulation which the patent laws have reserved to Congress.' Where state law offers 'patent-like protection for ideas deemed unprotected under the present federal scheme, [state law] conflicts with the strong federal policy favoring free competition in ideas.'" *Summit Mach. Tool Mfg. Corp. v. Victor CNC Sys., Inc.*, 7 F.3d 1434, 1439 (9th Cir. 1993) (citing *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 167 (1989)). But AB 824 is not offering patent-like protection; instead it is imposing a presumption of anti-competitiveness on certain types of patent settlements. A state law claim can survive federal patent law preemption so long as the state claim "contains an element not shared by the federal law; an element which changes the nature of the action so that it is qualitatively different from a copyright [or patent] infringement claim." *Summit Mach. Tool Mfg. Corp. v. Victor CNC Sys., Inc.*, 7 F.3d 1434, 1439-40 (9th Cir. 1993) (internal quotation omitted, brackets in original) (considering state law misappropriation claim in light of federal patent laws). AB 824 does not require a court to determine the validity or invalidity of a patent. Instead, it is focused on the payment of a "thing of value" to the generic drug company and attaches a presumption that such a transfer serves anti-competitive purposes. Because AB 824 does not require determination of the validity of a patent and does not create patent-like protections, it does not conflict with federal patent law and is therefore not preempted under this analysis.

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

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

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

Plaintiff notes the California Supreme Court acknowledged that the "United States Supreme Court is the final arbiter of questions of patent law and the extent to which interpretations of antitrust law — whether state or federal — must accommodate patent law's requirements . . . ." *In re Cipro Cases I & II*, 61 Cal. 4th 116, 142 (2015). Plaintiff posits that the finding in *Actavis* therefore precludes California from imposing its own antitrust laws on reverse payment patent settlements. However, the California Supreme Court determined that "the
15 lesson of *Actavis* is that nothing in the patent laws or the Hatch-Waxman Act dictates such a special *15 rule; that a settlement resolves a patent dispute does not immunize the agreement from antitrust attack;" and that if federal antitrust law can weigh the pro- and anti-competitive effects of a patent settlement without "offense to patent law, then so too can the state antitrust law." *In re Cipro Cases I & II*, 61 Cal. 4th at 161. This Court agrees with the California Supreme Court. The holding in *Actavis* allows the enforcement of antitrust law on patent settlements rather than foreclosing such enforcement.

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

Further, while *Actavis* applies the rule of reason to the analysis of reverse payment settlements under federal antitrust law, it does not establish exactly how and when this test should be applied. Instead, the Court in *Actavis* explicitly leaves the question of how to apply the rule it articulated to the lower courts. "As in other areas of law, trial courts can structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question — that of the presence of significant
16 *16 unjustified anticompetitive consequences. We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation." 570 U.S. at 159-60.

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

3. Excessive Fines

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

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

[4] The Court acknowledges Plaintiff's reference to the recent case of *Timbs v. Indiana*, 139 S. Ct. 682, 687-89 (2019), which holds the Excessive Fines Clause is fully incorporated against the states. The Court need not and does not determine whether such incorporation revokes the 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.

The parties agree that the Eighth Amendment prohibits states from imposing "excessive fines" and has been applied where the fine is imposed, in whole or in part, as punishment for an offense. The parties also do not dispute that the fine imposed under AB 824 is intended as a penalty and further agree that a fine is considered excessive if it is disproportionate to the gravity of the offense. In the Ninth Circuit, courts consider four factors in determining whether a penalty is grossly disproportionate to the offense: (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. (ECF No. 10 at 28; ECF No. 24 at 12; *see United States v. $132,245.00 in U.S. Currency*, 764 F.3d 1055, 1058 (9th Cir. 2014)).

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

Moreover, and as the parties agree, in evaluating a claim under the Excessive Fines Clause, "the standard of
18 gross disproportionality" requires a court to "compare the amount of the *18 forfeiture to the gravity of the [ ] offense. If the amount of the forfeiture is grossly disproportional to the gravity of the defendant's offense, it is unconstitutional." *Bajakajian*, 524 U.S. at 336-37. In the Ninth Circuit, this typically requires courts to consider the four factors articulated above: (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). 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 noted, "[t]he first factor requires review of the circumstances of the offense 'in great detail.'" *Crawford v. United States Dep't of the Treasury*, No. 3:15-CV-250, 2015 WL 5697552, at *14-15 (S.D. Ohio Sept. 29, 2015), (citing *Solem v. Helm*, 463 U.S. 277, 290-91 (1983) (Cruel and Unusual Punishments Clause analysis)). "In this case, there are no circumstances to review, because no . . . penalty has been imposed. A fact-specific determination of excessiveness is impossible where any wrongful conduct is hypothetical." *Id*. The same is true here.

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

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

Plaintiff fails to cite to any authority establishing that an as-applied pre-enforcement claim is cognizable under the Excessive Fines Clause. But assuming it is, the Court must nevertheless apply the three-part test articulated above with respect to pre-enforcement challenges generally. Specifically, in order to successfully establish that the claim is ripe for review, Plaintiff must show: (1) a concrete plan to violate the law; (2) a communicated threat of prosecution; and (3) a history of past prosecution or enforcement of the challenged law. As discussed above with respect to Plaintiff's claim under the Dormant Commerce Clause, Plaintiff does not sufficiently meet this standard. Even more so with respect to Plaintiff's "as-applied to individuals" claim, Plaintiff has made no attempt to proffer evidence that a single individual intends to violate AB 824, nor that the State has communicated a threat of levying a $20 million fine against, for example, a junior associate at a law firm who

took notes during settlement negotiations. Further, the prudential inquiry leads the Court to find the claim is unripe as it requires factual development. As a result, the Court finds Plaintiff's pre-enforcement as-applied to individuals attack is not yet ripe, and Plaintiff therefore fails to establish a likelihood of success on the merits of the claim.

Lastly, regardless of whether Plaintiff's Excessive Fines claim is intended as a facial or as-applied attack on the provision as it applies to individuals, any Excessive Fines claim requires a court to consider the four factors articulated above to determine if the fine is disproportionate to the gravity of the offense. Again, those factors
20 are: (1) the nature and extent of the violation; (2) *20 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); *see also Hoye*, 653 F.3d at 857 ("Because the difference between an as-applied and a facial challenge lies only in whether all or only some of the statute's subrules (or fact-specific applications) are being challenged, the substantive legal tests used in the two challenges are 'invariant.'") In the context of the $20 million fine as applied to individuals, Plaintiff comes closer to establishing possible success on this part of the inquiry. To be sure, the Court is troubled that a law firm's junior associate could theoretically face a $20 million fine for her participation in negotiating a settlement agreement that violates AB 824. But given the posture of this case, the Court cannot say Plaintiff has established a likelihood of success, or even raised serious questions going to the merits of its claim. As explained above, the analysis required to find an Excessive Fines Clause violation is fact-specific. Even narrowing the challenge to the statute as it applies to individuals, the Court cannot analyze the circumstances surrounding a violation before any violation occurs. Indeed, if a $20 million fine is levied against an individual in a case in which the four factors articulated above indicate such a fine is excessive, that individual may apply for a temporary restraining order or injunction and seek to invalidate the law as it is applied unconstitutionally to the individual. Absent those facts, the relief requested is premature. For those reasons, the Court finds Plaintiff has failed to establish a likelihood of success on the merits of its Excessive Fines claim. Further, even if Plaintiff had raised serious questions as to the merits of the claim, the balance of hardships does not tip significantly in Plaintiff's favor, as discussed below, such that a preliminary injunction should be granted.

4. Due Process

Finally, Plaintiff argues AB 824 violates due process because (1) it unfairly shifts the burden to the defendant to prove procompetitive effects; (2) the defendant's opportunity to rebut the presumptions imposed are meaningless because the statute presumes anticompetitive effects; and (3) relatedly, a manufacturer will not be able to prove an agreement *has had* procompetitive effects, even if that agreement *will* generate such effects
21 over time. (ECF No. 10 at 30-31.) In *21 opposition, the State argues: (1) the State has the authority to regulate legal procedure, including establishing a burden; (2) AB 824 expressly provides parties a meaningful opportunity to disprove liability once the burden is appropriately shifted; and (3) Plaintiff's position that the presumptions set forth in AB 824 represent a stark departure from established law is unsupported. (ECF No. 24 at 24-25.) In reply, Plaintiff seems to concede that a burden shift in and of itself is not violative of due process, clarifying that AB 824 is unconstitutional "because it shifts the burden of persuasion to the defendant *and also* imposes a presumption of guilt while making it effectively impossible to rebut that presumption." (ECF No. 27 at 13.) More specifically, Plaintiff cites to a scenario in which a generic settles a patent dispute by agreeing to an early but not immediate entry date with an exclusive license. The generic, Plaintiff claims, will have to prove that such an agreement *has* generated procompetitive benefits and that the benefits outweigh the anticompetitive effects presumed by the law. (*Id.*)

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

While seemingly an accurate statement of AB 824's language, the Court is not convinced that AB 824's express provision allowing a manufacturer to rebut the presumption by showing procompetitive effects is not meaningful. Here, it is Plaintiff's burden to establish a likelihood of success on its due process claim. But Plaintiff offers nothing in the way of caselaw or evidence supporting its stance that the process provided for by the statute is not meaningful. First, there are other means of disproving liability, including showing the value received is fair and reasonable compensation solely for other goods or services provided. Also, the parties remain free to invoke any other standard antitrust defense. And moreover, the fact that AB 824 demands a
22 showing that *22 a settlement "has directly generated procompetitive benefits"[5] does not render that option meaningless. Indeed, the Court can imagine a scenario where a settlement would have an immediately procompetitive effect. AB 824 simply reflects a desire to penalize parties that enter into agreements that — among other requirements — have not generated procompetitive benefits.

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

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

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

Finally, Plaintiff asserts AB 824's presumption that the relevant product market is limited to the branded drug
23 and its generic substitutes renders the anticompetitive presumption *23 irrebuttable because it deprives defendants of the opportunity to present every available defense. (ECF No. 10 at 39.) The Court disagrees. AB 824 simply erects a presumption regarding the relevant market. It does not foreclose the defendant from presenting evidence that the relevant market is broader than the one presumed. Granted, AB 824 seems to stack

certain presumptions on top of other presumptions. This may have the effect of making it more difficult to rebut all applied presumptions, but nothing indicates to the Court that it has the effect of depriving potential defendants of their due process rights. As a result, the Court finds Plaintiff has not established a likelihood of success on the merits of its due process claim, nor has it raised serious questions going to those merits. Even if Plaintiff had raised serious questions, as discussed below, the balance of hardships does not tip significantly in Plaintiff's favor such that a preliminary injunction should be granted.

B. Irreparable Injury

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

Plaintiff alleges its members will suffer irreparable injury because: (1) AB 824 violates Plaintiff's members' constitutional rights and they are therefore *per se* irreparably injured; (2) they will be forced to make a decision to either continually violate AB 824 and expose themselves to significant liability or litigate every patent dispute to judgment and carry the financial burden of doing so; and (3) as a result of AB 824 and the impossible choice presented by (2), Plaintiff's members will have no choice but to cease entering the market, leading to lost goodwill and damage to reputation. Moreover, Plaintiff asserts its members will be irreparably harmed by the imposition of a fine pursuant to AB 824 because the Eleventh Amendment prohibits parties from suing state officials, and therefore prevents recoupment of any unjustified payment. In response, the State emphasizes that Plaintiff's claimed injuries are purely speculative, and that any potential harm to Plaintiff's
24 members will be the result of their own *24 business choices, not the result of AB 824 itself. The State also argues that because Plaintiff has failed to demonstrate a likelihood of success on the merits of its constitutional claims, it has failed to demonstrate that it will suffer irreparable harm resulting from a constitutional violation.

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

Moreover, "[s]peculative injury does not constitute irreparable injury sufficient to warrant granting a preliminary injunction." *Caribbean Marine Servs. Co. v. Baldrige*, 844 F.2d 668, 674 (9th Cir. 1988) (citing *Goldie's Bookstore, Inc. v. Super. Ct.*, 739 F.2d 466, 472 (9th Cir.1984)). "A plaintiff must do more than merely allege imminent harm sufficient to establish standing; a plaintiff must demonstrate immediate threatened injury as a prerequisite to preliminary injunctive relief." *Id.* (citing *Los Angeles Memorial Coliseum Commission v. National Football League*, 634 F.2d 1197, 1201 (9th Cir.1980)). As discussed above in the context of Plaintiff's Dormant Commerce Clause claim, nowhere does Plaintiff point to a specific pending case or settlement

negotiation in which it will need to act differently as a result of AB 824 (nor is the Court convinced that a change in a drug manufacturer's business practices would constitute irreparable harm in any event). Speculation of how the market will react to the bill's implementation is not enough to support a preliminary injunction.

Most concerning to the Court is Plaintiff's claim that any fine improperly levied — especially with respect to an individual — could not be recouped because of the Eleventh Amendment's protection of state officials. But at this time, that injury is also speculative and not *25 imminent. Indeed, if the State were to pursue a $20 million fine against a minor individual participant in a violative settlement agreement, for example, that individual may be able to state a claim that the law violates the Excessive Fines Clause as applied to them and may be able to seek a preliminary injunction on those grounds. That, however, is not presently before the Court.

C. Balance of Hardships and Public Interest

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

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

The State, by contrast, asserts that AB 824 will lower prescription drug prices by closing a loophole in the Hatch-Waxman Act whereby brand-name drug companies are able to preserve otherwise weak patents by paying generic drug companies to keep their drugs off the market. *26 Under the State's analysis, closing this loophole will ensure that generic and brand companies no longer have an incentive to keep the generic off the market for longer than would be supported by the underlying patent and thus encourage the entry of cheaper generics onto the market faster. According to the State, AB 824 is designed to curb the high costs of prescription drugs.

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

VI. CONCLUSION

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

IT IS SO ORDERED. Dated: December 31, 2019

/s/_____

Troy L. Nunley

United States District Judge