No. 20-15014

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Plaintiff-Appellant,

v.

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

Defendant-Appellee.

On Appeal from the United States District Court
for the Eastern District of California,
No. 2:19-cv-02281-TLN-DB

BRIEF FOR PLAINTIFF-APPELLANT

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January 30, 2020

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, the undersigned counsel for Association for Accessible Medicines ("AAM") in the above-captioned matter makes the following disclosure statement:

AAM does not have any parent or affiliates; AAM is a membership organization. A list of AAM's current regular members is set forth below.

1. 3M Health Care Business
2. Accord Healthcare Inc.
3. American Regent
4. Amneal Pharmaceuticals Inc.
5. Apotex Corporation
6. Argentum Pharmaceuticals
7. Aurobindo Pharma USA Inc.
8. Bausch Health
9. Cipla USA
10. Dr. Reddy's Laboratories
11. Fresenius Kabi USA LLC
12. Glenmark Generics Inc., USA
13. Greenstone LLC, a subsidiary of Pfizer
14. Hikma Pharmaceuticals

15. Jubilant Cadista Pharmaceuticals, Inc.

16. Lupin Pharmaceuticals, Inc.

17. Mallinckrodt, Inc.

18. Mayne Pharma

19. Mylan N.V.

20. Rhodes Pharmaceuticals

21. Sagent Pharmaceuticals, Inc.

22. Sandoz, Inc., a Novartis Division

23. Sun Pharmaceutical Industries, Inc.

24. Teva Pharmaceuticals USA

25. Zydus Pharmaceuticals USA

Dated: January 30, 2020

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INTRODUCTION

This should have been the latest in "a long line of cases holding that states violate the Commerce Clause by regulating or controlling commerce occurring wholly outside their own borders." *Dean Foods Co. v. Brancel*, 187 F.3d 609, 615 (7th Cir. 1999); *see, e.g.*, *Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608, 614 (9th Cir. 2018); *Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1321-24 (9th Cir. 2015) (en banc); *NCAA v. Miller*, 10 F.3d 633, 640 (9th Cir. 1993). California Assembly Bill 824 ("AB 824") regulates settlement agreements resolving pharmaceutical patent infringement suits between brand-name drug companies and manufacturers of competing generic and biosimilar medicines. It imposes crippling financial penalties for violating its terms. And, unlike other recent California statutes, it is not limited to transactions completed in California or even connected to California. AB 824 is thus a textbook violation of the dormant Commerce Clause, which "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." *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989) (citation omitted).

The district court thought it "would likely violate the Dormant Commerce Clause" "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." ER 8. Of course it would. In *Sam Francis*,

this Court "easily conclude[d]" that a California law violated the dormant Commerce Clause to the extent it regulated out-of-state transactions. 784 F.3d at 1323. This case is even easier. Whereas the California statute in *Sam Francis* only applied to out-of-state transactions when "the seller resides in California," *id.* at 1322 (quoting Cal. Civ. Code § 986(a)), AB 824 applies to out-of-state agreements regardless of where the transacting parties are located. Likewise, whereas the California statute this Court enjoined in *Daniels Sharpsmart* applied to out-of-state transactions only when they dealt with waste generated in California, 889 F.3d at 612, AB 824 applies to out-of-state agreements regardless of where the medicines at issue were or will be made. In short, AB 824 does not merely "affect[] transactions that take place across state lines"; it directly regulates transactions "entirely outside of the state's borders," *id.* at 614, in "per se violation of the Commerce Clause," *Miller*, 10 F.3d at 640.

Although the district court did not contest that conclusion, it nonetheless found that "Plaintiff has not established a likelihood of success on the merits of" this claim "because it has not established that the issue is ripe for review." ER 8. That is not just incorrect, but contrary to fundamental principles of federal law.

The district court refused to "assume that California would" enforce AB 824 against a settlement entered out of state. ER 11. But this case requires no speculation. The Attorney General has steadfastly refused to disavow applying AB 824 to agreements entered out of state, despite being given multiple opportunities

both in the district court and in this Court. *See LSO, Ltd. v. Stroh*, 205 F.3d 1146, 1155 (9th Cir. 2000) ("the Government's failure to disavow application of the challenged provision [i]s a factor in favor of" Article III jurisdiction). As a result, regulated entities like the member-manufacturers of plaintiff-appellant Association for Accessible Medicines ("AAM") must act as if AB 824 applies nationwide.

Furthermore, AB 824 imposes multimillion-dollar penalties not just on companies that settle patent suits in violation of its terms, but on each individual who assists with a settlement later deemed a violation—down to the "junior associate or legal secretary working at the law firm representing one of the settling parties." ER 16. Given the ruinous financial consequences that could befall an individual for simply being a cog in a settlement that turns out to violate AB 824, common sense dictates that regulated entities will steer clear of settling patent disputes anywhere in the country on terms that might even arguably come within the statute's terms. AAM's members' declarations confirm that conclusion and underscore that so altering their conduct will cause them direct economic injury.

The decision below thus allows California to have its cake (by controlling AAM's members' out-of-state commercial conduct, in violation of the Commerce Clause) and eat it too (by skirting accountability for its unconstitutional overreach). Indeed, under the district court's conception of ripeness, the case may never be ripe, because no regulated entity will risk taking the actions the district court deemed

necessary to sufficiently ripen the dispute. Yet, as the uncontradicted record proves, AB 824 not only profoundly and adversely affects the behavior of parties outside California, but causes AAM's members direct economic injury.

The district court believed that the limitations of Article III compelled it to leave AAM's members subject to this Schrödinger's constitutional violation. But neither ripeness nor any other principle of law countenances that result, let alone compels it. A plaintiff in these circumstances "does not have to await the consummation of threatened injury to obtain preventive relief." *LSO*, 205 F.3d at 1154 (quoting *Blanchette v. Conn. Gen. Ins. Corps.*, 419 U.S. 102, 143 (1974)). Rather, a plaintiff need show only that it "intends to engage in 'a course of conduct arguably affected with a constitutional interest' and that there is a credible threat that the challenged provision will be invoked against the plaintiff." *Id.* at 1155 (quoting *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979)).

The Constitution protects the right to engage in commerce in State *A* unencumbered by the regulatory apparatus of State *B*. *Healy*, 491 U.S. at 335-36. Indeed, that protection is at the heart of the Constitution. *Okla. Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 180 (1995). There is likewise a credible threat of enforcement. AAM's members are engaged in scores of patent suits outside California, many more are in the pipeline, and the Attorney General has refused to disavow applying AB 824 to such cases. In any event, AAM's members will suffer

economic injury as a direct result of AB 824 even if the Attorney General's veiled threats never materialize into actual lawsuits. AAM's claim is therefore ripe and the district court committed a serious error by concluding otherwise. As such, AAM is likely to succeed on the merits of its dormant Commerce Clause claim.

Nor is this AB 824's only constitutional defect. The statute regulates patent settlements on terms that directly conflict with federal patent law, in defiance of the Supremacy Clause. The district court seemed to think that federal patent law preempts only state laws that "offer[] patent-like protection." ER 12-13. Not so. State laws that "upset the careful balance" of a federal scheme like patent law are preempted. *Edgar v. MITE Corp.*, 457 U.S. 624, 634 (1982). Specifically, state laws regulating "competition" have long been "held to be preempted by the federal patent law" when, as here, they "upset the federally struck balance." *Morseburg v. Balyon*, 621 F.2d 972, 977 (9th Cir. 1980). AB 824 upsets the careful balance Congress struck and the Supreme Court went out of its way to respect in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). Whereas *Actavis* rejected a presumption that patent settlements are anticompetitive whenever they contain "reverse payments" and do not allow immediate generic entry, *id.* at 158-59, AB 824 adopts the very presumption *Actavis* rejected. And, whereas the Patent Act expressly confers the right to grant exclusive licenses, AB 824 deems all "exclusive license[s]" to be presumptively anticompetitive. § 134002(a)(1)(A) (ER 98).

The district court waved away these conflicts, believing that "*Actavis* turns on questions of antitrust law, not patent law." ER 15. This was error. *Actavis* held that "patent and antitrust policies are both relevant" in determining whether a patent settlement is unlawful. 570 U.S. at 148. As such, even the California Supreme Court has recognized that the state "must abide by [*Actavis*'s] judgment" on "the extent to which" its own law "must accommodate patent law's requirements." *In re Cipro Cases I & II*, 348 P.3d 845, 859 (Cal. 2015). And it is difficult to imagine a regime less consistent with *Actavis*'s judgment on how to "accommodate patent law's requirements" than AB 824.

Given that AB 824 sweeps far beyond existing antitrust law, the exorbitant fines it imposes will render patent settlements prohibitively risky for generic manufacturers, which, unlike their brand-name counterparts, typically operate on thin margins. AB 824 will thus deter manufacturers not only from settling patent litigation, but from seeking approval for new generic medicines in the first place, given that such applications usually lead to patent litigation. AB 824 therefore stands as an obstacle to the operation of federal law that provides a pathway for generic medicines to enter the market, and it is therefore preempted on that basis as well. AB 824 also violates the Excessive Fines Clause, as penalties of *at least* $20 million are excessive vis-à-vis individuals who merely assist in settling patent suits. And AB 824 makes it effectively impossible to rebut its presumption of

anticompetitiveness, in violation of due process, which guarantees a meaningful opportunity to contest liability.

Finally, AB 824 will inflict untold harm on the very patients it seeks to help by severely delaying, or precluding altogether, access to lower-priced, life-saving generic and biosimilar medicines. Concrete injuries are occurring right now, as scores of patent suits pending outside California cannot be settled without risking the wrath of the California Attorney General. By denying AAM a preliminary injunction, the district court erred at every turn. This Court should reverse.

STATEMENT OF JURISDICTION

The district court had jurisdiction under 28 U.S.C. § 1331. This Court has jurisdiction over this timely preliminary injunction appeal under 28 U.S.C. § 1292(a)(1). *See* ER 33.

STATEMENT OF THE ISSUES

1. Whether AB 824, which directly regulates pharmaceutical patent settlements and is not limited to settlements in California, violates the dormant Commerce Clause, which bars states from regulating out-of-state transactions.

2. Whether AAM's members must wait for California to sue them in California state court before they may challenge AB 824 under 42 U.S.C. § 1983 and the U.S. Constitution, even though AB 824 is violating their constitutional rights and causing them economic injury right now.

3. Whether AB 824, which erects a presumption of anticompetitiveness in defiance of *Actavis*, conflicts with federal law; and whether it stands as an obstacle to the Hatch-Waxman Act by impeding the main pathway through which generic medicines enter the market.

4. Whether it is unconstitutionally excessive for a state to impose the risk of $20-million-plus penalties on individual persons who merely assist in settling patent lawsuits in a way that is consistent with federal law and policy.

5. Whether AB 824 violates due process by depriving defendants of a realistic opportunity to rebut liability.

6. Whether injunctive relief is warranted given that AAM's members suffer irreparable injury by the mere risk that AB 824 may be enforced against them, and given that the statute undermines the public interest by stemming the flow of affordable generic and biosimilar medicines to patients nationwide.

STATEMENT OF THE CASE

A. Factual and Legal Background

1. Patent settlements are integral to the entry of generic and biosimilar medicines into the market.

Access to generic and biosimilar medicines is critical to ensuring that Americans have affordable healthcare. In 2018, generics accounted for 90% of the prescriptions dispensed in the U.S. (up from 75% in 2009), but just 22% of total drug spending. Ass'n for Accessible Meds., *The Case for Competition: 2019 Generic*

The balance of this brief has been omitted for this sample.

For a complete version of this brief, please contact our office.

Thank you.