UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

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

Plaintiff Association for Accessible Medicines ("AAM") brings this complaint for declaratory and injunctive relief against Xavier Becerra, in his official capacity as Attorney General for the State of California (the "Attorney General"). AAM brings this complaint based on personal knowledge as to all AAM facts, and on information and belief as to all other matters.

PRELIMINARY STATEMENT

1. Generic and biosimilar medicines enhance Americans' access to lifesaving medications. They help drive down the often sky-high prices of brand-name drugs. Yet, under the federal patent system, these equally safe and effective—but far lower-priced—alternatives to brand-name drugs typically cannot enter the market until after the patents protecting brand-name drugs have expired or have been

successfully challenged in court. Patent settlements help shave years off brand-name drug companies' monopolies, *see, e.g.*, Declaration of Anne Wilson (Mylan Witness) ¶ 6 (Mylan's recent settlements alone "have shortened the brand's patent exclusivity by over 350 years"), and save everyday Americans billions of dollars every year as a result. Indeed, many generic and biosimilar medicines that have come to market prior to patent expiry in recent years would not have done so were it not for patent settlements.

2. Nor is there any viable alternative route to early entry of generic and biosimilar medicines, or to bringing down the cost of brand-name drugs more generally. To be sure, generic and biosimilar manufacturers theoretically could litigate every patent infringement suit to judgment. In reality, though, that is not a viable option. Patent litigation is incredibly expensive. As Chief Justice Roberts recently acknowledged, the cost of pharmaceutical patent litigation often exceeds $10 million per side. *FTC v. Actavis, Inc.*, 570 U.S. 136, 170 (2013) (Roberts, C.J., dissenting). Patent litigation is also incredibly time-consuming, with the average case taking many years from complaint to resolution. *See Ohio Willow Wood Co. v. Thermo-Ply, Inc.*, 629 F.3d 1374, 1376-77 (Fed. Cir. 2011) (Moore, J., concurring) ("As of 2009, 384 patent cases had been pending in the district courts for three years or more.").

3. Even in single-patent situations, those dollars and years add up. But it is increasingly rare for a high-value brand-name drug to be protected by only a single patent. Today, patents for pharmaceutical products are often backed up by large patent portfolios that include scores of follow-on patents. *See Proctor & Gamble Co. v. Paragon Trade Brands, Inc.*, 15 F. Supp. 2d 406, 414 n.6 (D. Del. 1998). Frequently, the only economical, procompetitive way to bring low-priced generic or biosimilar alternatives to market in the face of these types of large patent portfolios is through settlement agreements.

4. The follow-on portfolio for some brand-name drugs consists of more than ***100 separate patents***. Challenging all 100-plus patents would take tens (if not hundreds) of millions of dollars, and would take many years (if not more than a decade). In the interim, the brand-name drug would be the only game in town—free to charge patients on whose lives it depends monopolist prices. After all, even a single patent is enough to keep all less-expensive alternatives off the market.

5. Nor is it realistic to assume that every patent claim protecting a high-priced brand-name drug will be declared invalid or not infringed. A 2010 study found that generic manufacturers prevailed in ***less than half*** of the patent cases litigated to judgment. *See* RBC Capital Mkts., *Pharmaceuticals: Analyzing Litigation Success Rates* at 4 (Jan. 15, 2010), https://amlawdaily.typepad.com/pharmareport.pdf. Indeed, even as to secondary

and follow-on patents, patent claims are upheld just as often as they are invalidated. *See* Br. for the Generic Pharm. Ass'n as *Amicus Curiae* Supporting Respondents ("Actavis Br. for Generic Pharm."), *FTC v. Actavis, Inc.*, No. 12-416, 2013 WL 769341, at *16-*17 (U.S. Feb. 28, 2013).

6. Patent settlements, therefore, are often the only way to facilitate market entry of less-expensive generic and biosimilar alternatives to high-priced brand-name drugs prior to the expiration of all applicable brand-name drug patents. And if that cost-controlled mechanism for market entry is off the table, many generic and biosimilar manufacturers often will stay out of the market entirely until after patent expiry rather than be forced to muddle through ruinously expensive litigation challenging every patent in a portfolio.

7. Unfortunately, recently enacted California legislation, Assembly Bill No. 824 ("AB 824" or "the Act") (Exhibit A), threatens to render pharmaceutical patent settlements—and the dramatic price savings they help achieve—relics of the past.

8. California's first-of-its kind regulatory framework in AB 824 renders presumptively unlawful many (if not most) agreements that resolve pharmaceutical patent infringement suits, even if the agreement satisfies the test the Supreme Court laid out in *Actavis*; even if the FTC has reviewed and not challenged the agreement; and even if the agreement is between two non-California entities, is negotiated

entirely out of state, and is entered in an out-of-state court. Making matters worse, each person (not just each company) deemed to have assisted in a violation of the statute is liable for a penalty of no less than twenty million dollars, even if he or she received ***no value*** as a result of the settlement.

9. AB 824 will have perverse and far-reaching consequences for companies and patients alike. The presumption of illegality the statute erects—and the massive penalties it imposes—will create significant barriers to entry for generic and biosimilar medicines. The inevitable result will be far fewer such alternatives entering the market before patent expiry, resulting in ***less*** competition and ***higher*** prices for patients—exactly the opposite of what Congress sought to achieve in the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act" or "Hatch-Waxman"), Pub. L. No. 98-417, 98 Stat. 1585 (codified in various sections of titles 21, 35 & 42 U.S.C.), and the Biologics Price Competition and Innovation Act ("BPCIA"), Pub. L. No. 111-148, 124 Stat. 119, and exactly the opposite of what American patients need.

10. Nor is there any pressing need for state-level intervention. As the Chairman of the Federal Trade Commission ("FTC") (the federal agency responsible for antitrust enforcement in the pharmaceutical industry) recently emphasized, "despite a considerable increase in the total number of final Hatch-Waxman patent settlements in FY 2016," "'the Supreme Court's Actavis decision has ***significantly***

reduced the kinds of reverse payment agreements that are most likely to impede generic entry and harm consumers.'" FTC, *Press Release: FTC Staff Issues FY 2016 Report on Branded Drug Firms' Patent Settlements with Generic Competitors* (May 23, 2019) ("FTC Press Release") (emphasis added), http://bit.ly/2I1Rwof. In the wake of *Actavis*, in other words, the federal system is working precisely as intended: protecting the patent rights of brand-name drug manufacturers to reward their research and development, but at the same time encouraging the timely development and fostering the timely market entry of more affordable generic and biosimilar medicines.

11. AB 824 is thus a solution in search of a problem that, even in the eyes of the FTC, effectively no longer exists. And AB 824 is not just bad policy; it is also unconstitutional. AB 824 disrupts the careful balance Congress established in Hatch-Waxman and the BPCIA; it regulates commerce in other states (and indeed, across the entire country); and it imposes fines that are grossly excessive by any relevant measure. For these reasons, and as explained below, AAM seeks an injunction against the implementation and enforcement of the Act, a declaration that the Act is unconstitutional and invalid, and any other relief this Court deems appropriate.

THE PARTIES

12. AAM 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. AAM's core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medications. AAM's members provide Americans with generic drugs that are just as safe and effective as their brand-name counterparts but substantially less expensive. Indeed, in 2018 generic medicines like those produced by AAM's members saved Americans more than $5.6 billion ***every single week of the year***. *See* AAM, *The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report* at 4 (2019), https://bit.ly/2ojfghJ ("2019 Report").

13. AAM is authorized by its Board of Directors to bring this suit on its members' behalf.

14. Many AAM members have recently settled patent infringement disputes with brand-name manufacturers. *See, e.g.*, Declaration of Craig Kuchii ¶ 5; Declaration of Brij Khera ¶ 5; Declaration of Robert Matsuk ¶ 5; Wilson Decl. ¶ 6. Many AAM members are currently engaged in patent litigation brought by brand-name manufacturers in response to the filing of an abbreviated new drug application

with a Paragraph IV certification. *See, e.g.*, Declaration of Colman B. Ragan, Esq. ¶ 8; Khera Decl. ¶ 7; Wilson Decl. ¶ 7. And more still are developing generic counterparts to patented drugs and/or contemplating filing new abbreviated new drug applications with Paragraph IV certifications, *see, e.g.*, Kuchii Decl. ¶ 7; Ragan Decl. ¶ 10, which "means provoking [patent] litigation." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 407 (2012).

15. Likewise, many AAM members are currently engaged in patent litigation brought by the manufacturers of brand-name biologics, challenging the member's biosimilar as infringing. And others are currently developing biosimilar counterparts to patented biologics and/or contemplating filing new abbreviated Biologics License Applications, which, like abbreviated new drug applications, more often than not provoke patent litigation. *See, e.g.*, Ragan Decl. ¶¶ 8, 10.

16. Yet, in light of AB 824, some generic and biosimilar medicines that AAM members are currently developing will never see the light of day—at least not before the expiration of every relevant patent in the brand-name drug company's portfolio, which in many instances includes patents that have not yet been granted or disclosed. Given the sky-high costs of litigating patent-infringement suits to judgment and the large numbers of patents that protect a single drug, generic and biosimilar manufacturers like AAM's members depend on the availability of patent settlements to ensure that they will be able to recoup their investments in developing

new, low-priced medicines. If AB 824 remains on the books, however, many if not most AAM members will be forced to take immediate and drastic steps to ensure that they are not subjected to crippling state-law liability—including refraining from filing generic drug and biosimilar applications at all. *See*, *e.g.*, Khera Decl. ¶¶ 8-9; Kuchii Decl. ¶¶ 6-7; Matsuk Decl. ¶¶ 6-11; Ragan Decl. ¶¶ 9-10; Wilson Decl. ¶ 11.

17. Defendant Xavier Becerra is the Attorney General of the State of California. The Attorney General is responsible for enforcement and administration of AB 824. In enforcing and administering AB 824, the Attorney General (as well as those subject to his supervision, direction, and/or control) will at all relevant times be acting under color of state law. The Attorney General is a resident of California, and is sued only in his official capacity.

JURISDICTION AND VENUE

18. AAM's causes of action arise under 42 U.S.C. § 1983 and the United States Constitution. The Court has jurisdiction under 28 U.S.C. § 1331.

19. Venue is appropriate in this district pursuant to 28 U.S.C. § 1391(b).

BACKGROUND

Congress Has Created Finely Balanced Processes to Incentivize Both Medical Innovation and Competition Through the Patent and FDA Regulatory Systems

20. The costs of bringing a new lifesaving medicine to market are staggering. To obtain approval from the U.S. Food and Drug Administration ("FDA"), novel medicines must go through a period of rigorous testing and

disclosure, which typically takes several years and costs several billion dollars. *See* Matthew Herper, *The Cost of Creating A New Drug Now $5 Billion, Pushing Big Pharma To Change*, FORBES (Aug. 11, 2013), https://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/#16294a2713c3.

21. In light of the overwhelming expense of developing new medicines, pharmaceutical innovations would be few and far between if everyone could market and profit off every new invention immediately. That is where the patent system comes in. *See* Bret Dickey et. al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 ANNALS HEALTH L. 367, 369 (2010) ("The process of developing new drugs is lengthy, costly, and uncertain; as such, protection of the intellectual property rights underlying these innovations is critical to encouraging pharmaceutical manufacturers to continue to invest in R&D."). The basic right a patent confers on its owner is "the right to exclude others from profiting by the patented invention" for a limited period of time. *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980); *see* 35 U.S.C. §§ 154(a), 271(a), 365(c).

22. Throughout much of the twentieth century, federal law required all pharmaceutical drug products—even those that were similar in every way relevant to efficacy and safety to an already-approved brand-name drug—to undergo independent and rigorous clinical testing before they could go to market. *See, e.g.*,

Laura J. Robinson, *Analysis of Recent Proposals to Reconfigure Hatch-Waxman*, 11 J. INTELL. PROP. L. 47, 52 (2003). This regime left patent holders with an unintended windfall that hurt Americans. Given the significant costs of performing the required tests, generic drug manufacturers had little incentive to duplicate previously approved pharmaceutical products, since it would be difficult to recoup their initial investment. *See* H.R. Rep. No. 98-857(II) at 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688. Hundreds of brand-name drugs had no off-patent or generic equivalent, which left patients with little choice but to pay sky-high prices for basic medications long after the relevant patents had expired. Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993 (2007).

23. That changed in 1984, when Congress enacted the Hatch-Waxman Act. The Hatch-Waxman Act was intended "to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting); *see also* H.R. Rep. No. 98-857(I) (1984) at 14-15.

24. "To incentivize innovation"—and thus further the first of those policy objectives—"Hatch-Waxman grants brand manufacturers opportunities to extend their exclusivity period beyond the standard 20-year patent term: it allows a brand-

name manufacturer to seek a patent extension of up to five years to compensate for time that lapsed during the FDA regulatory process, 35 U.S.C. § 156, and an additional six-month period of 'pediatric exclusivity' if the manufacturer conducts certain pediatric studies, 21 U.S.C. § 355a." *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 644 (2d Cir. 2015).

25. To "promot[e] competition from generic substitute drugs"—and thus further the second of those policy objectives—Hatch-Waxman draws sharp distinctions between brand-name drugs and their generic equivalents. *Id.* On the one hand, the testing requirements for a new drug application ("NDA") remain rigorous. *See, e.g.*, 21 U.S.C. § 355(b)(1) (requiring, among other things, "full reports of investigations" into safety and effectiveness, "a full list of the articles used as components," and a "full description" of how the drug is manufactured, processed, and packed). On the other hand, generic manufacturers may file an abbreviated new drug application ("ANDA") that "piggy-back[s] on the brand's NDA." *Caraco*, 566 U.S. at 404-05.

26. "[T]he typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Id.* at 405; *see* 21 U.S.C. § 355(j)(2)(A)(ii)-(vii), (j)(8)(B) (generic drug is bioequivalent to a brand drug if "the rate and extent of absorption" of the active ingredient is the same as with the brand drug). "In this way the generic manufacturer can obtain approval

while avoiding the 'costly and time-consuming studies' needed to obtain approval 'for a pioneer drug.'" *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (quoting *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990)).

27. This streamlined process for approving generic medicines' entry onto the market has been remarkably successful in achieving Congress's goal of "'get[ting] generic drugs into the hands of patients at reasonable prices—fast.'" *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)). And, just as Congress intended, generics play a crucial role in controlling healthcare costs for Americans. Generic medicines now account for 90% of all prescriptions dispensed in the United States, but only 22% of the money spent on prescription drugs. 2019 Report at 4. Indeed, generic medicines saved Americans ***$2 trillion*** over the past decade, including $293 billion in 2018 alone. *Id.* Timely availability of generic drugs is thus critical to ensuring that patients have access to affordable medicine, and that the American healthcare system works for the benefit of all Americans.

28. In addition to "'speed[ing] the introduction of low-cost generic drugs to market,'" *Actavis*, 570 U.S. at 142 (quoting *Caraco*, 566 U.S. at 405), Hatch-Waxman "sets forth special procedures for identifying, and resolving, related patent disputes," *id.* at 143. As relevant here, Hatch-Waxman "requires the pioneer brand-name manufacturer to list in its New Drug Application the 'number and the

expiration date' of any relevant patent," and "requires the generic manufacturer in its Abbreviated New Drug Application to 'assure the FDA' that the generic 'will not infringe' the brand-name's patents." *Id.* (citation omitted); *see* 21 U.S.C. § 355(b)(1). As relevant here, a generic manufacturer can provide this "assurance" by "certify[ing]" under Paragraph IV "that any listed, relevant patent 'is invalid or will not be infringed by the manufacture, use, or sale' of the drug described in the Abbreviated New Drug Application." *Actavis*, 570 U.S. at 143 (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)).

29. Filing an ANDA with a Paragraph IV certification "automatically counts as patent infringement," *id.* (citing 35 U.S.C. § 271(e)(2)(A) (2006 ed., Supp. V)), and a generic applicant must notify the brand-name company if its ANDA contains a Paragraph IV certification, 21 U.S.C. § 355(j)(2)(B). "Filing a paragraph IV certification" thus often "means provoking litigation," *Caraco*, 566 U.S. at 407, but with the patent holder as the plaintiff and the would-be generic seller as the defendant. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.* ("*Cipro I*"), 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) (Hatch-Waxman "alter[ed] the litigation risks of patent lawsuits," putting the Hatch-Waxman defendant in the shoes traditionally worn by a plaintiff, and the plaintiff in the shoes traditionally worn by a defendant.).

30. "If the brand-name patentee brings an infringement suit within 45 days" of the filing of a Paragraph IV certification, *Actavis*, 570 U.S. at 143, "FDA generally

may not approve the ANDA until 30 months pass or the court finds the patent invalid or not infringed," which usually takes at least that long (if not longer), *Caraco*, 566 U.S. at 407. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Thus, "the mere filing" an ANDA with a Paragraph IV certification "can provide additional years of a generic-free market, regardless of the merits of the lawsuit." Elizabeth Powell-Bullock, *Gaming the Hatch-Waxman System: How Pioneer Drug Makers Exploit the Law to Maintain Monopoly Power in the Prescription Drug Market*, 29 J. LEGIS. 21, 26-27 (2002).

31. As originally enacted, the Hatch-Waxman Act did not allow generic manufacturers to counterclaim to challenge the validity of a patent, and "evidence mounted that some brands were exploiting this statutory scheme to prevent or delay the marketing of generic drugs." *Caraco*, 566 U.S. at 408. "Congress responded to these abuses by creating a mechanism, in the form of a legal counterclaim, for generic manufacturers to challenge patent information a brand has submitted to the FDA." *Id.*; *see* Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066, 2452.

Federal Law Likewise Ensures Timely Access to Lower-Cost Biosimilars

32. In addition to Hatch-Waxman, Congress enacted the BPCIA, which regulates "biologics"—large-molecule medicines derived from living organisms—and creates an expedited pathway to FDA approval for more affordable "biosimilar" alternatives. Enacted as part of the Patient Protection and Affordable Care Act of

2010, the BPCIA was intended to strike a balance between encouraging price competition within this rapidly growing category of expensive pharmaceuticals and incentivizing the development of new medicines.

33. To that end, the BPCIA regulates two types of biologics—brand-name reference products and follow-on biologics called biosimilars. Much like the Patent Act, the BPCIA guarantees brand-name companies a 12-year period of exclusivity for new biologics. 42 U.S.C. § 262(k)(7)(A). But, much like Hatch-Waxman, the BPCIA also establishes an abbreviated pathway for the regulatory approval of medicines that are "highly similar" to a reference product. *Id.* § 262(i)(2).

34. That abbreviated pathway is particularly critical to patients, and for a simple reason—biologics are incredibly expensive, even more so than typical brand-name drugs. "Fewer than 2% of all prescriptions are biologics, yet they account for 36% of total drug spending, comprising $125.5 billion in 2018, a 9.5% increase over 2017." 2019 Report at 16; *see also* Comment of the Staff of the FTC to FDA at 3 (Oct. 27, 2015) (biologic drugs on average cost ***22 times*** what traditional chemical or small-molecule medications cost).

35. To obtain FDA approval via the abbreviated pathway under the BPCIA, a biosimilar applicant must submit to the FDA an abbreviated Biologics License Application ("aBLA"), which, like an ANDA, relies in part on the reference product's already-FDA-approved license. 42 U.S.C. § 262(k). And like Hatch-

Waxman's Paragraph IV process, the BPCIA not only helps to speed biosimilar medicines to market, but also facilitates the resolution of patent disputes between biosimilar applicants and reference product sponsors by creating procedures that lead to early litigation (and thus resolution or settlement) of infringement claims. *See id.* § 262(*l*).

36. In sum, Congress has created a system composed of a number of federal statutes to balance two conflicting interests: (1) protecting the patent rights of brand-name drug manufacturers to reward and incentivize research and development; and (2) encouraging the timely development and market entry of more affordable generic and biosimilar medicines.

Patent Litigation Is Extraordinarily Expensive, Risky, and Ripe for Settlement

37. "[P]atent litigation is particularly complex, and particularly costly." *Actavis*, 570 U.S. at 170 (Roberts, C.J., dissenting); *see also, e.g.*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005) ("Patent litigation breeds a litany of direct and indirect costs"); *DeLaventura v. Columbia Acorn Trust*, 417 F. Supp. 2d 147, 153 n.7 (D. Mass. 2006) ("[P]atent litigation is the slowest and most expensive litigation in the United States."). Today, "an average patent case cost[s] upwards of ***$3 million*** for each side." *Ohio Willow Wood Co. v. Thermo-Ply, Inc.*, 629 F.3d 1374, 1376-77 (Fed. Cir. 2011) (Moore, J., concurring) (emphasis added). As a result, "[r]oughly ***$1 billion*** dollars is spent annually in the United States on

patent litigation." Steven C. Carlson, *Patent Pools and the Antitrust Dilemma*, 16 Yale J. on Reg. 359, 380 (1999) (emphasis added).

38. And there is no such thing as a sure thing when it comes to a lawsuit for patent infringement. *See, e.g.*, *Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J.) ("No one can be ***certain*** that he will prevail in a patent suit."), *dismissed*, 104 F. App'x 178 (Fed. Cir. 2004). Patent suits involve a "jungle of technology," with "conflicting expert testimony, technical evidence, and technical arguments." Morgan Chu & Joseph M. Lipner, *Adopting A Case Theme*, in PATENT LITIGATION STRATEGIES HANDBOOK 41 (Barry L. Grossman & Gary M. Hoffman, eds. 2000). As such, courts have long recognized that "patent cases may well be the most difficult for [juries] to understand." *Cooper Indus., Inc. v. Juno Lighting, Inc.*, No. 85 C 7243, 1987 WL 15086, at *6 (N.D. Ill. Jan. 28, 1987), *aff'd* 826 F.2d 1073 (Fed. Cir. 1987); *see also Cipro I*, 261 F. Supp. 2d at 208 ("[I]t is [always] a gamble to place a technology case in the hands of a lay judge or jury…. [T]here are risks involved even in that rare case with great prospects." (citation omitted)).

39. Both of those factors (high cost and uncertainty) are especially apparent in Paragraph IV litigation. The cost of Paragraph IV litigation often exceeds ***$10 million***, three times the average patent case. *Actavis*, 570 U.S. at 170 (Roberts, C.J., dissenting). Biosimilar patent suits are significantly more expensive. And

"[o]utcomes of drug patent infringement suits are notoriously unpredictable and error prone." Chika Seidel, *Comment, Settlement Should Be the End of the Story: A Proposed Procedure to Settle Hatch-Waxman Paragraph IV Litigations Modeled After Rule 23 Class Action Settlement Procedure*, 46 SETON HALL L. REV. 697, 705 (2016).

40. Moreover, the risks of patent litigation are enormous, especially for generic and biosimilar manufacturers. If an ANDA filer loses a Paragraph IV suit—which, despite the increasing number of follow-on patents, happens more often than not when cases are litigated to the judgment, *see* Actavis Br. for Generic Pharm. at 16 (citing 2010 study showing that generic manufacturers prevailed in ***only 82 of 171*** patent infringement cases litigated to judgment in the prior decade)—its generic product cannot enter the market until after patent expiry, regardless of future events. *See* 35 U.S.C. § 271(e)(4)(A). And even when a generic or biosimilar manufacturer ***wins*** an infringement suit in district court, it can still face crippling financial liability if it launches the product only to have the Federal Circuit subsequently reverse. *See, e.g.*, Peter Loftus, *Teva Faces Possible Damages From Selling Generic Protonix*, WALL ST. J. ONLINE (Feb. 13, 2013) (noting that Apotex was found liable for $442 million in damages despite its product having been on the market for a mere 23 days), https://on.wsj.com/2lTMByh; *see also* RBC Capital Markets,

Pharmaceuticals: Analyzing Litigation Success Rates at 7 (Jan. 15, 2010) (Federal Circuit reverses or vacates, at least in part, nearly half of the patent appeals it hears).

41. Furthermore, generic and biosimilar manufacturers typically operate on thin margins. Yet those margins would quickly turn from black to red if a manufacturer had to litigate every patent in the relevant portfolio whenever it filed an ANDA. Nor would generic and biosimilar manufacturers be able to continue financing those new applications if they came with the prospect of $10 million litigation (or more). The settlement off-ramp, in other words, is a key component in the economic calculus that Hatch-Waxman and the BPCIA created.

42. Unsurprisingly, then, the rate of settlement in patent suits generally—and in Paragraph IV and aBLA suits in particular—has traditionally outpaced the rate of settlement in the rest of civil litigation.

43. Nor has that changed in the wake of the Supreme Court's decision in *Actavis*. *See* Bureau of Competition, FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2016* at 1 (May 2019) ("FY 2016 Overview") ("During fiscal year 2016 (October 1, 2015 to September 30, 2016), pharmaceutical companies filed 232 agreements constituting final resolution of patent disputes between brand and generic pharmaceutical

manufacturers, significantly more than any other year since enactment of the [MMA]."), https://bit.ly/2moUyf2.

***The Federal Government Regulates Pharmaceutical Patent Settlements under the Antitrust Framework the Supreme Court Established in* FTC v. Actavis**

44. The facts that gave rise to the Supreme Court's decision in *Actavis* began when a brand-name manufacturer (Solvay) filed a New Drug Application for a new pharmaceutical product called AndroGel, which the FDA approved. *Actavis*, 570 U.S. at 144. A few years later, a generic manufacturer (Actavis) "filed an Abbreviated New Drug Application for a generic drug modeled after AndroGel," and "certified under paragraph IV that [the] listed patent was invalid and [Actavis's] drugs did not infringe it." *Id.* Another generic manufacturer (Paddock) did the same shortly thereafter. *Id.* at 144-45. Solvay responded by "initiat[ing] paragraph IV patent litigation against Actavis and Paddock." *Id.* at 145.

45. Faced with rising litigation costs and uncertain prospects, the parties ultimately settled. "Under the terms of the settlement," Solvay authorized Actavis, the first ANDA filer (who therefore stood to enjoy a 180-day period of generic exclusivity), to bring its generic to market "65 months before Solvay's patent expired." *Id.* Actavis and Paddock also agreed "to promote AndroGel." *Id.* In return for those promises and "for other services the generics promised to perform," "Solvay agreed to pay millions of dollars to each generic." *Id.*; *see* Seidel, *supra*, at 699 ("pharmaceutical settlements" often "include a complex mix of side deals as

well as non-monetary considerations," including licenses, co-development agreements, and manufacturing, supply, and distribution agreements); *see also* FY 2016 Overview (summarizing recent pharmaceutical settlements).

46. Upon settlement, the parties reported the terms of the settlement to the Federal Trade Commission ("FTC") and the Antitrust Division of the Department of Justice, as required by Hatch-Waxman and the MMA. *Actavis*, 570 U.S. at 152. After reviewing the agreement, the FTC filed suit against the settling parties, alleging that they violated federal antitrust law (specifically section 5 of the FTC Act) "by unlawfully agreeing 'to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years.'" *Id.* at 145. *See generally FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986) (Section 5 of FTC Act "encompass[es] … practices that violate the Sherman Act and the other antitrust laws."); 15 U.S.C. § 45(a)(1) (Section 5 of FTC Act) ("Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful."). The district court dismissed the FTC's complaint, and the Eleventh Circuit affirmed. *Actavis*, 570 U.S. at 146.

47. At the Supreme Court, the FTC "urge[d the Court] to hold that reverse payment settlement agreements"—*i.e.*, settlements in which the patentee agrees to provide anything of value to the alleged infringer (*e.g.*, the ANDA filer)—"are

presumptively unlawful and that courts reviewing such agreements should proceed via a 'quick look' approach, rather than applying a 'rule of reason.'" *Id.* at 158-59. The Supreme Court "decline[d] to do so." *Id.* at 159. As it explained, settlements with terms permitting a generic to enter the market before the expiration of the patent will often "bring about competition … to the consumer's benefit." *Id.* at 154.

48. Accordingly, although the Court held that patent settlements do not receive ***absolute*** antitrust immunity whenever they allow the generic to enter a patentee's market prior to patent expiry, *see id.* at 153-58, it made clear that not all patent settlements are inherently suspect, *see id.* at 158 (emphasizing that its holding "does not prevent litigating parties from settling their lawsuit," including "by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration"). The Court offered several examples of payments that should escape antitrust scrutiny, including: (1) payments that are "no more than rough approximation" of avoided litigation expenses; (2) payments that "reflect compensation for other services that the generic has promised to perform--such as distributing the patented item or helping to develop a market for that item"; (3) payments that reflect "traditional settlement considerations"; and (4) payments that offer "any other convincing justification." *Id.* at 156, 159.

49. Under *Actavis*, only those settlements that contain "***large and unjustified***" reverse payments trigger any antitrust scrutiny at all. *Id.* at 158

(emphasis added). As the Court explained, such "unexplained large reverse payment[s]" will "normally suggest that the patentee has serious doubts about the patent's survival," and only "[a] *valid* patent excludes all except its owner from the use of the protected process or product." *Id.* at 147, 157-58 (emphasis in original).

50. The Court also explained that "the likelihood [that] a reverse payment" will ***actually*** "bring[] about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification," and "[t]he existence and degree of any anticompetitive consequence may also vary as among industries." *Id.* at 159.

51. Finally, *Actavis* held that even in a case involving a patent settlement that includes a "large and unexplained" payment from the patentee to the ANDA filer, the challenger "***must prove its case as in other rule-of-reason cases***," and only those patent settlements that ***actually*** carry "significant anticompetitive effects" will violate that standard. *Id.* at 157, 159 (emphasis added). *See Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018) ("The rule of reason requires courts to conduct a fact-specific assessment of 'market power and market structure … to assess the [restraint]'s ***actual effect***' on competition." (emphasis added; ellipsis and alteration in original) (quoting *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768 (1984))); Marc G. Schildkraut, Actavis *and the Burden of Proof: Antitrust*

Revolution, A Muddle, or Both, 33-SPG Antitrust 56, 56-57 (2019) (Under the rule of reason, "detailed examination" of alleged anticompetitive effects "is always necessary"; plaintiffs bear the burden to "prove that the challenged agreement had an actual anticompetitive effect.").

52. Since *Actavis* and subsequent FTC action, the total number of patent settlement agreements per year has ***increased***, while the number of potentially anticompetitive agreements per year has declined, according to the FTC's own count, to only one. *See* FTC Press Release. The federal system is therefore working. Companies have reacted to the lines drawn in *Actavis* and establishing a place of equilibrium where procompetitive settlements can and still do happen, but anticompetitive settlements typically do not.

AB 824 Upsets* Actavis*'s Delicate Balance and is Inconsistent with the Federal Standards for Determining Whether Patent Settlements Are Permissible

53. Notwithstanding *Actavis*—and the fact that it "has significantly reduced the kinds of reverse payment agreements that are most likely to impede generic entry and harm consumers," *id.*—California's new law renders presumptively unlawful many (if not most) agreements that resolve or settle a pharmaceutical patent infringement claim.

54. Under AB 824, "an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical

product, shall be presumed to have anticompetitive effects and shall be a violation of this section if both of the following apply:

> (A) A nonreference drug filer receives anything of value from [the] company asserting patent infringement ….
>
> (B) The nonreference drug filer agrees to limit or forego research, development, manufacturing, marketing, or sales of [its] product for any period of time."

§ 134002(a)(1); *see* § 134000(d) (defining "agreement resolving or settling a patent infringement claim" to mean "any agreement that is entered into within 30 days of the resolution or the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim"); § 134000(g) (defining "[n]onreference drug filer" to mean a generic or biosimilar manufacturer).

55. The statute defines the term "anything of value" to mean all transfers of value, except "consideration granted by the brand or reference drug filer to the nonreference drug filer" that "consists of only one or more of the following":

> (A) The right to market the competing product in the United States before the expiration of [the brand's relevant patent].
>
> (B) A covenant not to sue on a claim that the nonreference drug product infringes a United States patent.

(C) Compensation for saved reasonable future litigation expenses of the reference drug holder but only if both of the following are true:

> (i) The total compensation for saved litigation expenses is reflected in budgets that the reference drug holder documented and adopted at least six months before the settlement.
>
> (ii) The compensation does not exceed the lower of … $7,500,000 [or] [f]ive percent of the revenue that the nonreference drug holder projected or forecasted it would receive in the first three years of sales of its version of the reference drug documented at least 12 months before the settlement ….

(D) An agreement resolving or settling a patent infringement claim that permits a nonreference drug filer to begin selling, offering for sale, or distributing the nonreference drug product if the reference drug holder seeks approval to launch, obtains approval to launch, or launches a different dosage, strength, or form of the reference drug having the same active ingredient before the date set by the agreement for entry of the nonreference drug filer. A different form of the reference drug does not include an authorized generic version of the reference drug.

(E) An agreement by the reference drug holder not to interfere with the nonreference drug filer's ability to secure and maintain regulatory

> approval to market the nonreference drug product or an agreement to facilitate the nonreference drug filer's ability to secure and maintain regulatory approval to market the nonreference drug product.
>
> (F) An agreement resolving a patent infringement claim in which the reference drug holder forgives the potential damages accrued by a nonreference drug holder for an at-risk launch of the nonreference drug product that is the subject of that claim."

§ 134002(a)(2); *see also* § 134002(a)(1)(A) (the term "anything of value" includes, "but [is] not limited to, an exclusive license or a promise that the brand company will not launch an authorized generic version of its brand drug").

56. To rebut the anticompetitive-effects presumption set forth in § 134002(a)(1), a party must prove by a preponderance of the evidence that "[t]he value received by the nonreference drug filer" as part of the agreement "is a fair and reasonable compensation ***solely for other goods or services*** that the nonreference drug filer has promised to provide," or that "[t]he agreement has directly generated procompetitive benefits ***and*** the procompetitive benefits of the agreement outweigh [its] anticompetitive effects." § 134002(a)(3) (emphases added).

57. Section 134002(b) specifically instructs that, "[i]n determining whether" that burden has been met, a finder of fact "shall not presume":

> (1) That entry into the marketplace could not have occurred until the expiration of the relevant patent exclusivity or that the agreement's provision for entry of the nonreference drug product before the expiration of any patent exclusivity means that the agreement is procompetitive ….
>
> (2) That any patent is enforceable and infringed by the nonreference drug filer in the absence of a final adjudication binding on the filer of those issues.
>
> (3) That the agreement caused no delay in entry of the nonreference drug filer's drug product because of the lack of [FDA] approval of that or of another nonreference drug product.
>
> (4) That the agreement caused no harm or delay due to the possibility that the nonreference drug filer's drug product might infringe some patent that has not been asserted against the nonreference drug filer or that is not subject to a final and binding adjudication on that filer as to the patent's scope, enforceability, and infringement.

58. AB 824 contains no language limiting its application to settlement agreements between California entities. Nor does it contain language limiting its application to agreements negotiated, signed, and/or entered in California court.

59. AB 824 also imposes extremely severe individual penalties. "Each person that violates or assists in the violation of this section" and who "received any value due to that violation" "shall forfeit and pay to the State of California a civil penalty" of "up to three times the value received by the party that is reasonably attributable to the violation of this section, or twenty million dollars ($20,000,000), whichever is greater." § 134002(e)(1)(A). And "[e]ach person that violates or assists in the violation of this section" and who "has ***not*** received any value" due to that violation "shall forfeit and pay to the State of California a civil penalty" of "up to three times the value given to other parties to the agreement reasonably attributable to the violation of this section, or twenty million dollars ($20,000,000), whichever is greater." *Id*. (emphasis added).

60. Only "the Attorney General" and "attorneys designated by it" for suing on its behalf may sue to collect that penalty. § 134002(e)(1)(B).

61. Governor Newsom signed AB 824 into law on October 7, 2019.

62. AB 824 is scheduled to take effect by operation of law (and thus begin to intrude on patent litigation nationally) on January 1, 2020.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
(Declaratory/Injunctive Relief—Commerce Clause—Extraterritoriality)

63. AAM re-alleges and incorporates by reference the preceding allegations as though fully set out herein.

64. In light of the Framers' "special concern both with the maintenance of a national economic union unfettered by state-imposed limitations on interstate commerce and with the autonomy of the individual States within their respective spheres," the Supreme Court has long held that, under the Commerce Clause, no state may "control[] commerce occurring wholly outside [its] boundaries." *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 335-36 (1989) (footnote omitted). As such, a state law that has "'the practical effect' of regulating commerce occurring wholly outside [the] State's borders" not only "exceeds the inherent limits of the enacting State's authority," but will be struck down under the Commerce Clause "***whether or not the regulated commerce has effects within the State***." *Id.* at 336 (emphasis added).

65. As the Ninth Circuit recently clarified, a state or local law "directly regulates interstate commerce" in violation of the Commerce Clause "when it 'directly affects transactions that take place across state lines or entirely outside of the state's borders." *Rosenblatt v. City of Santa Monica*, --- F.3d ---, 2019 WL 4867397, at *4 (9th Cir. Oct. 3, 2019) (quoting *S.D. Myers, Inc. v. City & Cty. of S.F.*, 253 F.3d 461, 467 (9th Cir. 2001)). AB 824 transgresses that limitation by its plain terms.

66. AB 824 extends to commerce (namely, patent settlements) negotiated, signed, and entered wholly outside the borders of California. AB 824 contains no restrictions that would limit its application to settlement agreements between

California entities, and no restrictions that would limit its application to settlement agreements that were negotiated, completed, or entered in California. And, as noted, AB 824 subjects the signatories to patent settlements to sweeping monetary penalties. AB 824 thus on its face "directly affects transactions that take place across state lines," in "per se violation of the dormant Commerce Clause." *Id.*

67. To be sure, AB 824 does not ***expressly*** refer to out-of-state commerce. But that is of no moment. The Supreme Court has plainly held that the fact that a state law "is addressed only to" conduct "in [the state] ***is irrelevant*** if the 'practical effect'" is to regulate conduct "in other States." *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986) (emphasis added); *see also Sam Francis Found. v. Christie's, Inc.*, 784 F.3d 1320 (9th Cir. 2015) (en banc) ("easily conclud[ing]" that California statute that regulated terms of sales of artworks outside of California, simply because the seller resided in California, violated the Commerce Clause, despite not mentioning other states). And AB 824 just as plainly reaches transactions (namely settlement agreements) that involve only non-California companies and that are completed entirely outside California. *See, e.g.*, Declaration of Jack C. Silhavy ¶ 4 (patent settlements "in most instances" were between two non-California entities, completed entirely outside of California, and "governed by the laws of other states"). Yet unlike traditional state antitrust law, which may authorize remedies or allow the use of procedural devices that are unavailable under

federal law, AB 824 imposes an entirely different substantive standard on transactions that take place entirely outside of California.

68. Finally, under AB 824, a settlement between an out-of-state brand-name manufacturer and an out-of-state generic or biosimilar manufacturer in a case involving no California party, that was negotiated in another state and entered in an out-of-state court, could be deemed unlawful in California, but lawful everywhere else—***including the state where it was entered***. The Commerce Clause protects against precisely that sort of morass. *See Healy*, 491 U.S. at 336-37 (Clause "protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State"); *see also id.* at 336 ("[T]he practical effect of the statute must be evaluated not only by considering the consequences of the statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation.").

69. AB 824 therefore violates the Commerce Clause as applied to settlement agreements that were not negotiated, completed, or entered in California.

SECOND CAUSE OF ACTION
(Declaratory/Injunctive Relief—Preemption)

70. AAM re-alleges and incorporates by reference the preceding allegations as though fully set out herein.

71. Federal law is "the supreme Law of the Land; … any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. Art. IV, cl. 2.

72. Any state statute or regulation that "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" is therefore invalid. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); *see Wyeth v. Levine*, 555 U.S. 555, 565 (2009) ("[T]he purpose of Congress is the ultimate touchstone in every pre-emption case." (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996))); *see also PLIVA, Inc. v. Mensing*, 564 U.S. 604, 621 n.6 (2011) ("[P]urposes-and-objectives pre-emption is a form of conflict pre-emption.").

73. Consistent with the "stated objective of the Constitution in granting the power to Congress to legislate in the area of intellectual property," the federal patent laws "offer[] a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974); *see* U.S. Const. Art. I, § 8, cl. 8. "The productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens." *Kewanee Oil Co.*, 416 U.S. at 480; *see, e.g., Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917) ("[T]he primary

purpose of our patent laws is … 'to promote the progress of science and useful arts.'" (quoting U.S. Const. Art. I, § 8, cl. 8)).

74. The objectives of Hatch-Waxman are similar but distinct. In enacting Hatch-Waxman, Congress "attempted to balance the goal of 'mak[ing] available more low cost generic drugs' with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement." *King Drug Co. v. SmithKline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015) (quoting H.R. Rep. No. 98–857, pt. 1, at 14-15 (1984)). Hatch-Waxman "facilitates" the development and market entry of generic drugs "by allowing an applicant to file" ANDAs, which are far "less onerous and less costly" than NDAs. *Id.* at 395; *see also Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (Congress's aim in enacting Hatch-Waxman was to "'get generic drugs into the hands of patients at reasonable prices—fast.'" (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991))).

75. In addition to regulating patents and pharmaceuticals, Congress has long regulated anticompetitive conduct that results in higher prices for patients. *See, e.g.*, Sherman Act, ch. 646, 26 Stat. 209 (1890) (codified as amended in 15 U.S.C. §§ 1-7). Indeed, "[t]he balance between the interest in motivating innovation and enlightenment by rewarding invention with patent protection on the one hand, and the interest in avoiding monopolies that unnecessarily stifle competition on the other, has been a feature of the federal patent laws since their inception." *Pfaff v. Wells*

Elecs., Inc., 525 U.S. 55, 63 (1998); *see also id.* ("[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology.").

76. To be sure, the Supreme Court "has recognized that the federal antitrust laws do not preempt state law" in every instance, as "Congress intended the federal antitrust laws to supplement, not displace, state antitrust remedies." *California v. ARC Am. Corp.*, 490 U.S. 93, 101-02 (1989). The Supreme Court has thus allowed states to impose penalties on conduct that would be unlawful under federal law, including penalties that go above and beyond what federal law allows. But "federal courts have not hesitated to rule that state antitrust law is preempted by federal law when they determine that state law comes into conflict with some ***other*** federal statute," such as federal patent law or the Hatch-Waxman Act. Richard A. Samp, *The Role of State Antitrust Law in the Aftermath of* Actavis, 15 MINN. J.L. SCI. & TECH. 149, 150 (2014) (emphasis added); *see, e.g.*, *Connell Constr. Co., Inc. v. Plumbers & Steamfitters Local Union No. 100*, 421 U.S. 616, 635-36 (1975) (claim arising under state antitrust law preempted by federal labor law even though conduct that gave rise to state claim could proceed under federal antitrust law). And even the California Supreme Court has recognized that, because "[t]he 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," states "must abide by [its] judgment" on those issues. *In re Cipro Cases I & II*, 348 P.3d 845, 859 (Cal. 2015).

77. *Actavis* could not be clearer about the contours of that "judgment" here. *Actavis* emphasized that, in reviewing antitrust challenges to patent settlements, courts must "balance" the competing interests of antitrust law and the federal patent laws, including Hatch-Waxman. As the Court explained, "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent." *Actavis*, 570 U.S. at 148; *cf. United States v. Line Material Co.*, 333 U.S. 287, 310 (1948) (requiring courts to make "an adjustment between the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by" antitrust law).

78. Consistent with that required "balance," *Actavis* expressly rejected the argument that all settlements that include any transfer of value from the brand company to the generic should be "presumptively unlawful." 570 U.S. at 158-59; *see* Saul P. Morgenstern, Adam M. Pergament, *Commentary: Applying the Rule of Reason in the Post*-Actavis *World*, 2018 COLUM. BUS. L. REV. 45, 69 (2018) ("The *Actavis* holdings … are clear—no *per se* rules, no quick looks, no presumptions."). What is more, the Court held that antitrust review of patent settlements is appropriate only in narrow circumstances—*viz.*, where the settlement contains a "large and unexplained" payment from the patent holder to the patent challenger—and, even

then, that antitrust review is appropriate only pursuant to the rule of reason. *Actavis*, 570 U.S. at 158-59. As the Court made clear, "abandonment of the 'rule of reason' in favor of presumptive rules (or a 'quick-look' approach) is appropriate only where 'an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on consumers and markets.'" *Id.* at 159 (quoting *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999) (Breyer, J., concurring in part and dissenting in part)).

79. Yet, under AB 824, nearly all patent settlements—even those with no "large and unexplained" payment from the patentee—are presumptively unlawful.

80. Under AB 824, only two conditions must be met for a patent settlement between a brand-name manufacturer and a generic manufacturer to be "presumed to have anticompetitive effects and [to] be a violation of" state law: (A) the generic manufacturer "receives anything of value" from the brand-name manufacturer; and (B) the generic manufacturer "agrees to limit or forego research, development, manufacturing, marketing, or sales" of its generic version of the drug "for any period of time." § 134002(a)(1). The term "anything of value"—which the statute defines to "includ[e]," *inter alia*, "a promise that the brand company will not launch an authorized generic version of its brand drug"—is obviously more capacious than the "large and unexplained" payments to which *Actavis* limited its holding. *Id*.

81. And as recent data from the FTC make clear, the second condition of § 134002(a) will be satisfied in the overwhelming majority of pharmaceutical patent settlements. In 195 (or more than 84%) of the 232 final settlements the FTC reviewed between October 1, 2015 and September 30, 2016 (the last period for which it has released data), the generic manufacturer agreed to the entry of its product at some time in the future. *See* FY 2016 Overview.

82. The FTC further found that most patent settlements also contain acceleration clauses, which allow settling generics to enter the market ***even earlier than initially agreed*** if certain agreed-upon conditions come to fruition. Such clauses appear to provide "value" to generic or biosimilar developers within the meaning of the new statute, even though they also accelerate competition.

83. Under the broad terms of AB 824, however, even those (and other, similar) types of contract terms that accelerate generic or biosimilar market entry could potentially trigger the statute's draconian presumption of illegality, notwithstanding the fact that such terms are procompetitive on their face. Indeed, ***most*** small and easily explained "transfers of value" from a brand-name drug company to a generic or biosimilar developer will trigger the statute's presumption of illegality—in direct violation of the federal standards set forth in *Actavis*.

84. The inevitable effect of allowing AB 824 to go into effect will be to scuttle dozens of patent settlements that are fully legal under *Actavis*. Hardly any

generic drug manufacturer (or their attorneys and signatories, who are individually liable under the statute) will be willing to risk a "penalty" of the greater of "$20,000,000" or "three times the value received" in a patent settlement, *see* § 134002(e)(1)(A), especially given that such penalties are not exclusive of other monetary liability under California (or federal) law, *see* § 134002(e)(2).

85. The resulting decline in patent settlements would be diametrically contrary to the careful balance between antitrust law and patent law that, according to the Supreme Court in *Actavis*, Congress sought to achieve.

86. The follow-on effects would conflict even more with Congress' aims. If generic and biosimilar manufacturers know in advance that any acceptable patent litigation settlement is likely to trigger potentially crippling liability under California law, then generic drug and biosimilar manufacturers will be far less likely to invest the time and money necessary to file aBLAs and Paragraph IV ANDAs in the first place. *See, e.g.*, Khera Decl. ¶¶ 8-9; Kuchii Decl. ¶¶ 6-7; Matsuk Decl. ¶¶ 6-11; Ragan Decl. ¶¶ 9-10; Wilson Decl. ¶¶ 10-11. After all, such filings trigger almost certain patent litigation. If generic and biosimilars were forced to spend $10 million ***per patent*** litigating cases to judgment before their less-expensive products could come to market, the generic and biosimilar medicines on which Americans rely every day would cease to be available prior to patent expiry in all but the most extraordinary cases. Such delays of generic drug and biosimilar entry will harm our

entire healthcare system—most notably patients, who will be forced to contend with monopoly prices for brand-name prescription drugs for longer periods of time.

87. AB 824 thus undermines both the rights conferred in patent law (*e.g.*, the right to grant exclusive licenses) and the pre-expiry market entry of generic drugs. That is contrary to the purposes of patent law generally and the Hatch-Waxman Act and BPCIA in particular. *Actavis* itself made clear that its holding should not be construed as impinging upon any other "right" that the patent laws grant patentees, "whether expressly or by fair implication." 570 U.S. at 151. And yet, under AB 824, settling a patent suit by exercising the long-established right of a patent holder to grant a competitor an exclusive license—*i.e.*, an authorization allowing the competitor to ***enter*** the market before patent expiry in exchange for payment ***from*** the competitor, *see* 35 U.S.C. § 261—is now grounds for potential state law liability whenever it is coupled with some other consideration. *See* § 134002(a)(1)-(2). That undermines not only the rights that federal patent law confers, but also the timely entry of lower-priced generic medicines onto the market.

88. That is no small conflict. The Supreme Court rejected the FTC's argument that all patent settlements that convey a thing of value to the generic manufacturer should be considered presumptively unlawful precisely because the Court concluded that many (if not most) such settlements will be *pro*competitive. After all, the entry of a generic drug onto the market often brings down prices for

patients by many orders of magnitude. In other words, the Court rejected a presumption of illegality because the "balance" between antitrust law and patent law must be taken into account in reviewing patent settlements, and presuming illegality could suppress economically useful conduct in contravention of the purposes of antitrust law. Yet AB 824 implements an even-less-solicitous variant of the argument the Supreme Court rejected in *Actavis*. AB 824 is thus irreconcilable with the purposes of the federal law that governs pharmaceuticals.

89. AB 824 stands as an obstacle to federal law in yet another way. In holding that the balance federal law erects between the patents and antitrust, *Actavis* rejected any form of antitrust review less solicitous than the rule of reason. Yet, under AB 824, it is ***the settling parties'*** burden to "demonstrate by a preponderance of the evidence that either" (A) "The value received by the nonreference drug filer … is a fair and reasonable compensation solely for other goods or services that [it] has promised to provide" or (B) "The agreement has directly generated procompetitive benefits and the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement." § 134002(a)(3). If the evidence on those issues is in equipoise, then the settling parties lose, and "[e]ach person who [thereby] violated" the statute (or who "assist[ed] in the violation") will be liable for "a civil penalty" of no less than $20 million. § 134002(e)(1)(A).

90. Finally, AB 824 vitiates patent rights that federal law expressly confers. Federal patent laws give patent holders the right to grant competitors exclusive licenses—*i.e.*, authorizations allowing competitors to enter the market before patent expiry in exchange for payment. *See* 35 U.S.C. § 261. The Supreme Court has long recognized the validity of such grants, *see, e.g.*, *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 127 (1938), and *Actavis* clearly admonished that such rights should be respected. Indeed, *Actavis* held that the kind of "reverse payments" it addressed could be subject to antitrust attack only after the United States assured the Court that such payments were entirely unlike "an exclusive license," which "is expressly authorized by the Patent Act, in Section 261 of Title 35." Oral Arg. Tr. 3-4, *FTC v. Actavis, Inc.*, No. 12-416 (U.S. Mar. 25, 2013). Nevertheless, AB 824 treats the grant of an exclusive license as presumptively anticompetitive, in direct conflict to the federal system.

91. AB 824 therefore stands as an obstacle to the accomplishment and execution of the full purposes and objectives of federal law, and is preempted as a result.

THIRD CAUSE OF ACTION
(Declaratory/Injunctive Relief—Excessive Fines Clause)

92. AAM re-alleges and incorporates by reference the preceding allegations as though fully set out herein.

93. The Eighth Amendment prohibits states from imposing "excessive fines." U.S. Const. amend. VIII; *Timbs v. Indiana*, 139 S. Ct. 682, 687 (2019). In particular, the Excessive Fines Clause prevents the government from levying civil penalties that are disproportionate to the underlying conduct and that serve a non-remedial purpose. *United States v. Bajakjian*, 524 U.S. 321, 328-34 (1998); *Austin v. United States*, 509 U.S. 602, 610 (1993); *see also WCI, Inc. v. Ohio Dep't of Pub. Safety*, 774 F. App'x 959, 967 (6th Cir. 2019) ("If the fine is intended as a punishment—even if only intended partially as a punishment, and partially for other reasons—the protections of the Eighth Amendment apply.").

94. There is no question that AB 824 imposes penalties for what it perceives as wrongdoing. Under AB 824, "[e]ach person that violates ***or assists in the violation*** of this section shall forfeit and pay to the State of California a civil ***penalty***" of no less than "twenty million dollars ($20,000,000)." § 134002(e)(1)(A) (emphases added). Section 134002 is also clear that the "penalty" must be "sufficient to deter violations of this section." *Id.* "In the excessive-fines context," however, it is clear that "a fine may constitute punishment when, for example, it does not serve a remedial purpose such as replacing revenue lost by the government," but instead seeks (even in part) to deter wrongdoing. *Sabri Props, LLC v. City of Minneapolis*, No. 18-cv-3098 (MJD/HB), 2019 WL 2052597, at *3 (D. Minn. May 9, 2019). Finally, only "the Attorney General" and "attorneys

designated by it" for suing on its behalf, not private parties, may sue to collect that "penalty." § 134002(e)(1)(B). The penalty thus goes to the state, not to any private party—just like classic forfeiture penalties. In sum, § 134002(e)(1)(A)'s "penalty" is clearly intended at least partially as a punishment, and is thus a "fine" within the meaning of the Eighth Amendment's Excessive Fines Clause. *See United States v. Mackby*, 261 F.3d 821, 829-31 (9th Cir. 2001) (civil monetary penalty under False Claims Act partially punitive and therefore subject to Excessive Fines Clause).

95. Nor is there any question that AB 824's penalty is excessive. A fine is excessive within the meaning of the Eighth Amendment when it is "grossly disproportional to the gravity of a defendant's offense." *Bajakjian*, 524 U.S. at 334. And here, the ***minimum*** penalty AB 824 authorizes for all "person[s]" that merely "***assist[] in [a] violation*** of" the statute is $20,000,000, ***even if the person "has not received any value" due to that violation***. § 134002(e)(1)(A) (emphasis added). Nor is there any de minimis requirement or textual criteria for determining what constitutes "assistance" that triggers the $20,000,000-or-more penalty. To the contrary, under the plain text of the statute, ***all*** persons that assist in a party's violation—not just all "parties" deemed to violate it—may be punished to the tune of $20,000,000 apiece, even if they gained not a dime as a result of the violation. It is difficult to fathom a more obvious violation of the Excessive Fines Clause.

96. While that is AB 824's most obvious Eighth Amendment violation, it is not the only unconstitutional aspect of AB 824's penalty provisions. The upper limit the statute authorizes—"three times the value received by the party that is reasonably attributable to the violation of this section," § 134002(e)(1)(A)(i)—often will amount to hundreds of millions of dollars. While in some truly outstanding cases that amount may be permissible, the upper bound is grossly excessive in relation to the purported anticompetitive harms of a patent settlement that allows a low-priced generic or biosimilar medicine to enter the market prior to patent expiry.

97. The penalties AB 824 imposes are therefore unconstitutional.

FOURTH CAUSE OF ACTION
(Declaratory/Injunctive Relief—Due Process—Burden-Shifting)

98. AAM re-alleges and incorporates by reference the preceding allegations as though fully set out herein.

99. AB 824 places "the burden of persuasion—the notion that if the evidence is evenly balanced, the party that bears the burden of persuasion must lose"—on the defendant, even in suits brought by the Attorney General seeking massive monetary penalties. *See Dir., Office of Workers' Comp. Programs, Dep't of Labor v. Greenwich Collieries*, 512 U.S. 267, 272 (1994).

100. Under AB 824, it is ***the settling parties'*** burden to "demonstrate by a preponderance of the evidence that either" (A) "The value received by the nonreference drug filer … is a fair and reasonable compensation solely for other

goods or services that [it] has promised to provide" or (B) "The agreement has directly generated procompetitive benefits and the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement." § 134002(a)(3). If the evidence on those issues is in equipoise, the settling parties lose, and "[e]ach person who [thereby] violated" the statute (or who "assist[ed] in the violation") will be liable for "a civil penalty" of no less than twenty million dollars and potentially far more. § 134002(e)(1)(A). "[D]ue process forbids" a state from "from shifting the burden of persuasion to defendants" in this way. *Back v. U.S. Dep't of Agric.*, 445 F. App'x 826, 829 (6th Cir. 2011) (citation omitted).

101. Making matters worse, in practical effect AB 824 deprives defendants in patent litigation from having "'an opportunity to present every available defense,'" in violation of due process. *See Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007) (quoting *Lindsey v. Normet*, 405 U.S. 56, 66 (1972)). Given that the statute begins from the premise that any settlement agreement that falls within its terms is anticompetitive, it is difficult to imagine how a manufacturer would go about demonstrating that an agreement "directly generated procompetitive benefits [that] outweigh [its] anticompetitive effects." § 134002(a)(3)(B). That is particularly true given that most modern patent settlements are complex and, as such, take years to be fully completed. In many cases, a generic manufacturer will not be

able to show that a settlement ***already has*** "generated" benefits even though the settlement undoubtedly ***will*** have procompetitive benefits over its lifetime.

102. AB 824 is therefore contrary to basic notions of procedural due process.

FIFTH CAUSE OF ACTION
(42 U.S.C. § 1983 and 42 U.S.C. § 1988)

103. AAM re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

104. An actual "Case or Controversy" exists because the Act's unconstitutional provisions create a genuine, credible, and immediate threat that the Attorney General—acting in his official capacity under color of state law—will violate the constitutionally protected rights of AAM and its members.

105. The injuries AAM seeks to remedy on behalf of its members are "'actual or imminent, not conjectural or hypothetical.'" *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)). This is not a case where it is merely possible that the alleged injuries will occur. To the contrary, there is ***at least*** "'a substantial risk that the harm will occur.'" *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013)); *see, e.g.*, Khera Decl. ¶¶ 8-9; Kuchii Decl. ¶¶ 6-7; Matsuk Decl. ¶¶ 6-11; Ragan Decl. ¶¶ 8-10; Wilson Decl. ¶ 11.

106. As the FTC recently recognized, "82 percent of final [patent] settlements" in FY 2016 conveyed something of value to "the generic company"

other than the early right to enter the market covered by the challenged patent. FTC Press Release. Yet, under AB 824, all patent settlements that convey "anything of value from [the] company asserting patent infringement" to the generic or biosimilar are presumptively unlawful. § 134002(a)(1). The majority of patent settlements therefore appear to fall within the new statute's ambit.

107. Patent settlements provide generic and biosimilar companies with essential procompetitive benefits that could not be achieved through expensive, years-long litigations. In addition to patent monopolies, drug products are subject to regulatory exclusivities that prevent the FDA from approving generic drug applications. Thus, even if a generic manufacturer believes it can invalidate the brand-name drug's patents, it may still be blocked from launching its product through a regulatory exclusivity.

108. Nor is the danger posed by AB 824 limited to settlements already completed. If the only way for generic and biosimilar medicines to enter the market prior to patent expiry is for manufacturers to litigate ***every*** patent protecting a brand-name drug all the way to final judgment, then few generic and biosimilar manufacturers will even try to launch a competing product before all of the patents protecting it expire. And if nearly ***every*** patent settlement—even those that do not contain "large and unexplained" payments from the patent holder to the generic or biosimilar—opens up all settling parties ***and every person*** that merely assisted in

hammering out the settlement to massive monetary penalties, then there will be far fewer patent litigation settlements. *See, e.g.*, Khera Decl. ¶¶ 8-9; Kuchii Decl. ¶¶ 6-7; Matsuk Decl. ¶¶ 6-9; Ragan Decl. ¶¶ 9-10; Wilson Decl. ¶ 10.

109. Nor can AAM's members afford to take a wait-and-see approach. Unlike brand-name drug companies, generic and biosimilar manufacturers operate on thin margins. Under AB 824, however, miscalculating the relative benefits of a patent settlement comes with drastic consequences. Even if a generic or biosimilar manufacturer gains the right to bring its lower-priced alternative to market before patent expiry—which is inarguably procompetitive—it can still find itself liable for a penalty of "three times the value received" in the settlement if a California jury determines that an even more procompetitive agreement could have been reached. § 134002(e)(1)(A). Yet the value received in such a settlement is often the only thing that allows a generic or biosimilar manufacturer to spend the time and money developing the low-priced alternative in the first place.

110. Absent this Court's intervention, then, AB 824 will radically reshape the nationwide market for lifesaving medicines and other pharmaceuticals. It will make it significantly harder for generic drug and biosimilar developers to settle patent litigation, and it will cause AAM's members immediately to reevaluate and alter their development programs. AB 824 thus will harm AAM's members

economically. More importantly, it will harm patients, by decreasing timely access to more affordable prescription medicines.

111. AAM accordingly seeks a declaration that the implementation or enforcement of the Act would violate 42 U.S.C. § 1983. AAM also seeks reasonable attorneys' fees pursuant to 42 U.S.C. § 1988.

PRAYER FOR RELIEF

WHEREFORE, AAM prays:

A. For a declaration, pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, that the Acts violate the United States Constitution and is therefore void and unenforceable;

B. For a preliminary injunction prohibiting the Attorney General from implementing and enforcing the Act;

C. For a permanent injunction prohibiting the Attorney General from implementing and enforcing the Act;

D. For such costs and reasonable attorney's fees to which it might be entitled by law; and

E. For any other relief that the Court deems just and proper.

Dated: November 12, 2019

KIRKLAND & ELLIS LLP

/s/ Matthew D. Rowen

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Attorneys for
Association for Accessible Medicines

JS 44 (Rev. 02/19)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Association for Accessible Medicines

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Matthew D. Rowen, Kirkland & Ellis LLP, 1301 Pennsylvania Avenue, NW, Washington, DC 20004, (202) 389-5000

DEFENDANTS

Xavier Becerra, in his official capacity as Attorney General of the State of California

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☒ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
42 U.S.C. § 1983

Brief description of cause:

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
11/12/2019

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

EXHIBIT A

STATE OF CALIFORNIA
LEGISLATIVE COUNSEL BUREAU
AUTHENTICATED
ELECTRONIC LEGAL MATERIAL

Assembly Bill No. 824

CHAPTER 531

An act to add Division 114.01 (commencing with Section 134000) to the Health and Safety Code, relating to business.

[Approved by Governor October 7, 2019. Filed with Secretary of State October 7, 2019.]

LEGISLATIVE COUNSEL'S DIGEST

AB 824, Wood. Business: preserving access to affordable drugs.

The Cartwright Act makes every trust, subject to specified exemptions, unlawful, against public policy, and void and defines "trust" for purposes of the act as a combination of capital, skill, or acts by 2 or more persons, defined as corporations, firms, partnerships, and associations, for certain designated purposes. Under existing law, these purposes include creating or carrying out restrictions in trade or commerce or preventing competition in manufacturing, marketing, transportation, sale, or purchase of merchandise, produce, or any commodity. The Unfair Practices Act makes certain business practices unlawful, including unfair competition. Under existing law, unfair competition is defined to include an unlawful, unfair, or fraudulent business act or practice, unfair, deceptive, untrue, or misleading advertising, and any false representations to the public.

This bill would provide that an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product, is to be presumed to have anticompetitive effects if a nonreference drug filer receives anything of value, as defined, from another company asserting patent infringement and if the nonreference drug filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the nonreference drug filer's product for any period of time, as specified. The bill would provide various exceptions to this prohibition, including, among others, if the agreement has directly generated procompetitive benefits and the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement. The bill would make a violation of these provisions punishable by a civil penalty that is recoverable only in a civil action brought by the Attorney General, as specified. The bill would provide that a violator is liable for any other remedies available under the Cartwright Act, the Unfair Practices Act, or the unfair competition law. The bill would require a cause of action to enforce those provisions be commenced within 4 years after the course of action accrued. The bill would define various terms for these purposes.

The people of the State of California do enact as follows:

SECTION 1. Division 114.01 (commencing with Section 134000) is added to the Health and Safety Code, to read:

DIVISION 114.01. PRESERVING ACCESS TO AFFORDABLE DRUGS

134000. For purposes of this division:

(a) "ANDA" means abbreviated new drug application.

(b) "ANDA filer" means a party that owns or controls an ANDA filed with the Food and Drug Administration or has the exclusive rights under that ANDA to distribute the ANDA product.

(c) "Agreement" means anything that would constitute an agreement under California state law or a "trust" under the Cartwright Act (Chapter 2 (commencing with Section 16700) of Division 7 of the Business and Professions Code).

(d) "Agreement resolving or settling a patent infringement claim" includes any agreement that is entered into within 30 days of the resolution or the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim. This shall include, but is not limited to, the following:

(1) Any agreement required to be provided to the Federal Trade Commission or the Antitrust Division of the United States Department of Justice under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173).

(2) Any agreement between a biosimilar or interchangeable product applicant and a reference product sponsor under the Biologics Price Competition and Innovation Act of 2009 (BPCIA) (Public Law 111-148) that resolves patent claims between the applicant and sponsor.

(e) "Biosimilar biological product application filer" means a party that owns or controls a biosimilar biological product application filed with the Food and Drug Administration under Section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) for licensure of a biological product as biosimilar to, or interchangeable with, a reference product, or that has the exclusive rights under the application to distribute the biosimilar biological product.

(f) "NDA" means new drug application.

(g) "Nonreference drug filer" means either:

(1) An ANDA filer.

(2) A biosimilar biological product application filer.

(h) "Nonreference drug product" means the product to be manufactured under an ANDA that is the subject of the patent infringement claim, a biosimilar biological product that is the product to be manufactured under

the biosimilar biological product application that is the subject of the patent infringement claim, or both.

(i) "Patent infringement" means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition, and extensions thereof.

(j) "Patent infringement claim" means any allegation made to a nonreference drug filer, whether or not included in a complaint filed with a court of law, that its nonreference drug product or application infringes any patent held by, or exclusively licensed to, the reference drug holder.

(k) "Reference drug holder" means either:

(1) A brand holder that is any of the following:

(A) The holder of an approved NDA for a drug product application filed under Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

(B) A person owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the "FDA Orange Book") in connection with the NDA.

(C) The predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with, any of the entities described in subparagraph (A) or (B), with control to be presumed by direct or indirect share ownership of 50 percent or greater, as well as the licensees, licensors, successors, and assigns of each of those entities.

(2) A biological product licenseholder, which means any of the following:

(A) The holder of an approved biological product license application for a biological drug product under Section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(B) A person owning or controlling enforcement of any patents that claim the biological product that is the subject of the approved biological patent license application.

(C) The predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with, any of the entities described in subparagraph (A) or (B), with control to be presumed by direct or indirect share ownership of 50 percent or greater, as well as the licensees, licensors, successors, and assigns of each of those entities.

(*l*) "Reference drug product" means the product to be manufactured by the reference drug holder and includes both branded drugs of the NDA holder and the biologic drug product of the biologic product license applicant.

(m) "Statutory exclusivity" means those prohibitions on the approval of drug applications under clauses (ii) through (iv), inclusive, of Section 505(c)(3)(E) (5-year and 3-year data exclusivity), Section 527 (orphan drug exclusivity), or Section 505A (pediatric exclusivity), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E), 360cc, and 355a, respectively) or on the licensing of biological product applications under Section 262(k)(7) of Title 42 of the United States Code (12-year exclusivity)

or Section 262(m)(2) or (3) of Title 42 of the United States Code (pediatric exclusivity).

134002. (a) (1) Except as provided in paragraph (3), an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product, shall be presumed to have anticompetitive effects and shall be a violation of this section if both of the following apply:

(A) A nonreference drug filer receives anything of value from another company asserting patent infringement, including, but not limited to, an exclusive license or a promise that the brand company will not launch an authorized generic version of its brand drug.

(B) The nonreference drug filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the nonreference drug filer's product for any period of time.

(2) As used in subparagraph (A) of paragraph (1), "anything of value" does not include a settlement of a patent infringement claim in which the consideration granted by the brand or reference drug filer to the nonreference drug filer as part of the resolution or settlement consists of only one or more of the following:

(A) The right to market the competing product in the United States before the expiration of either:

(i) A patent that is the basis for the patent infringement claim.

(ii) A patent right or other statutory exclusivity that would prevent the marketing of the drug.

(B) A covenant not to sue on a claim that the nonreference drug product infringes a United States patent.

(C) Compensation for saved reasonable future litigation expenses of the reference drug holder but only if both of the following are true:

(i) The total compensation for saved litigation expenses is reflected in budgets that the reference drug holder documented and adopted at least six months before the settlement.

(ii) The compensation does not exceed the lower of the following:

(I) Seven million five hundred thousand dollars ($7,500,000).

(II) Five percent of the revenue that the nonreference drug holder projected or forecasted it would receive in the first three years of sales of its version of the reference drug documented at least 12 months before the settlement. If no projections or forecasts are available, the compensation does not exceed two hundred fifty thousand dollars ($250,000).

(D) An agreement resolving or settling a patent infringement claim that permits a nonreference drug filer to begin selling, offering for sale, or distributing the nonreference drug product if the reference drug holder seeks approval to launch, obtains approval to launch, or launches a different dosage, strength, or form of the reference drug having the same active ingredient before the date set by the agreement for entry of the nonreference drug filer. A different form of the reference drug does not include an authorized generic version of the reference drug.

(E) An agreement by the reference drug holder not to interfere with the nonreference drug filer's ability to secure and maintain regulatory approval to market the nonreference drug product or an agreement to facilitate the nonreference drug filer's ability to secure and maintain regulatory approval to market the nonreference drug product.

(F) An agreement resolving a patent infringement claim in which the reference drug holder forgives the potential damages accrued by a nonreference drug holder for an at-risk launch of the nonreference drug product that is the subject of that claim.

(3) Parties to an agreement are not in violation of paragraph (1) if they can demonstrate by a preponderance of the evidence that either of the following are met:

(A) The value received by the nonreference drug filer described in subparagraph (A) of paragraph (1) is a fair and reasonable compensation solely for other goods or services that the nonreference drug filer has promised to provide.

(B) The agreement has directly generated procompetitive benefits and the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.

(b) In determining whether the parties to the agreement have met their burden under paragraph (3) of subdivision (a), the factfinder shall not presume any of the following:

(1) That entry into the marketplace could not have occurred until the expiration of the relevant patent exclusivity or that the agreement's provision for entry of the nonreference drug product before the expiration of any patent exclusivity means that the agreement is procompetitive within the meaning of subparagraph (B) of paragraph (3) of subdivision (a).

(2) That any patent is enforceable and infringed by the nonreference drug filer in the absence of a final adjudication binding on the filer of those issues.

(3) That the agreement caused no delay in entry of the nonreference drug filer's drug product because of the lack of federal Food and Drug Administration (FDA) approval of that or of another nonreference drug product.

(4) That the agreement caused no harm or delay due to the possibility that the nonreference drug filer's drug product might infringe some patent that has not been asserted against the nonreference drug filer or that is not subject to a final and binding adjudication on that filer as to the patent's scope, enforceability, and infringement.

(5) This subdivision shall not be construed to preclude a party from introducing evidence regarding paragraphs (1) to (4), inclusive, and shall not be construed to preclude the factfinder from making a determination regarding paragraphs (1) to (4), inclusive, based on the full scope of the evidence.

(c) In determining whether the parties to the agreement have met their burden under paragraph (3) of subdivision (a), the factfinder shall presume that the relevant product market is that market consisting of the brand or reference drug of the company alleging patent infringement and the drug

product of the nonreference company accused of infringement and any other biological product that is licensed as biosimilar or is an AB-rated generic to the reference product.

(d) (1) This section does not modify, impair, limit, or supersede the applicability of the antitrust laws of California as defined in the Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code), the Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code), or the unfair competition law (Chapter 5 (commencing with Section 17200) of Part 2 of Division 7 of the Business and Professions Code), or the availability of damages or remedies provided therein. This section does not modify, impair, limit, or supersede the right of any drug company applicant to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition of the federal antitrust law or state law.

(2) If any provision of this division, an amendment made to this division, or the application of any provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this division, the amendments made to this division, and the application of the provisions of this division or amendments to any person or circumstance shall not be affected.

(e) (1) (A) Each person that violates or assists in the violation of this section shall forfeit and pay to the State of California a civil penalty sufficient to deter violations of this section, as follows:

(i) If the person who violated this section received any value due to that violation, an amount up to three times the value received by the party that is reasonably attributable to the violation of this section, or twenty million dollars ($20,000,000), whichever is greater.

(ii) If the violator has not received anything of value as described in clause (i), an amount up to three times the value given to other parties to the agreement reasonably attributable to the violation of this section, or twenty million dollars ($20,000,000), whichever is greater.

(iii) For purposes of this subdivision, “reasonably attributable to the violation” shall be determined by California’s share of the market for the brand drug at issue in the agreement.

(B) Any penalty described in subparagraph (A) shall accrue only to the State of California and shall be recovered in a civil action brought by the Attorney General in its own name, or by any of its attorneys designated by it for that purpose, against any party to an agreement that violates this section.

(2) Each party that violates or assists in the violation of this section shall be liable for any damages, penalties, costs, fees, injunctions, or other remedies that may be just and reasonable and available under the Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code), the Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code), or the unfair competition law (Chapter 5

(commencing with Section 17200) of Part 2 of Division 7 of the Business and Professions Code), as applicable.

(3) If the State of California is awarded penalties under subparagraph (A) of paragraph (1), it may not recover penalties pursuant to another law identified in paragraph (2). This section shall not be construed to foreclose the State of California's ability to claim any relief or damages available in paragraph (2), other than those that are penalties.

(4) An action to enforce a cause of action for a violation of this section shall be commenced within four years after the cause of action accrued.

SEC. 2. The provisions of this act are severable. If any provision of this act or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

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