Association for Accessible Medicines

Your Generics & Biosimilars Industry

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Dear Senator Maroney, Representative D'Agostino, and Members of the General Law Committee:

The Association for Accessible Medicines (AAM) is the leading trade association for manufacturers of generic and biosimilar prescription medicines. AAM's core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medicines.

AAM respectfully opposes Senate Bill 269 ("SB 269") as drafted. SB 269 regulates settlement agreements resolving pharmaceutical patent-infringement suits between brand-name drug companies and manufacturers of competing generic medicines.[1] Specifically, SB 269 "presume[s]" that all such settlement agreements "have anticompetitive effects" and "violat[e]" Connecticut law, unless they allow a generic medicine to enter the market immediately and without any exclusivity, even against other generic manufacturers.

AAM recognizes the need to address prescription drug prices and supports efforts to suppress truly anticompetitive behavior. As drafted, however, SB 269 overreaches by penalizing **procompetitive** settlement agreements that significantly expedite generic and biosimilar access. By disincentivizing procompetitive, pro-patient settlement agreements, SB 269 will ultimately lead to increased pharmaceutical litigation costs, increased drug prices, and delayed patient access to more affordable versions of lifesaving medicines.

Furthermore, **SB 269 is unconstitutional**. The bill appears to directly regulate commerce beyond Connecticut's boundaries, in violation of the Commerce Clause, U.S. Const., Art. I, § 8, cl. 3. The bill regulates patent litigation settlements on terms that conflict with the federal patent laws, in violation of the Supremacy Clause, *id.* Art. VI, cl. 2. The bill imposes multimillion-dollar penalties on each individual who merely assists with a settlement later deemed a violation, which likely violates the Excessive Fines Clause, *id.* amend. VIII. And the bill makes it effectively impossible in practice to rebut its threshold presumption of anticompetitiveness, in violation of the Due Process Clause, *id.* amend. XIV, § 1, which guarantees a meaningful opportunity to contest liability.

RELEVANT BACKGROUND

Under SB 269, "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" whenever the generic manufacturer (i) "receives anything of value from [the brand] company" and (ii) "agrees to limit or forgo … sales of [its] product for any period of time." § 2(a)(1)(A). The statute defines the term "anything of value" broadly. Although it excludes various forms of compensation,

[1] By its terms, SB 269 also applies to settlement agreements between biologic manufacturers and biosimilar manufacturers. A biologic is derived from "biological sources such as animals or microorganisms," rather than "from chemicals"; a "biosimilar" is essentially a generic version of a biologic. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669-70 (2017).

the exclusions are narrow. "Compensation for saved reasonable future litigation expenses of the [brand-name drug company]" is excluded, but only if the "saved litigation expenses [are] reflected in budgets that [the brand-name drug company] documented and adopted at least 6 months before the settlement"—but, even then, "[i]f no projections or forecasts" were documented, "the compensation [may] not exceed $250,000." § 2(a)(2)(C). Similarly, various types of agreements that allow a generic manufacturer to introduce its generic medicine onto the market entry prior to patent expiry on **non-exclusive** terms are also excluded. *See* § 2(a)(2)(A). In contrast, SB 269 specifically "includ[es]" any form of "an exclusive license" in the definition of "anything of value." § 2(a)(1)(A).

SB 269 also measures delay from the date a settlement is entered, not against what would have happened if the underlying patent lawsuit were litigated to judgment. So, unless a settlement allows a generic manufacturer to bring its generic medicine onto the market immediately and without exclusivity, the settlement is presumptively unlawful, even if the brand-name drug is protected by secondary patents that were not at issue, and thus could not have been invalidated, in the underlying patent litigation. § 2(a)(2)(B).

The bill also makes it very difficult in practice for settling parties to rebut this threshold presumption of anticompetitiveness. A settling party must prove that "[t]he value received by the [generic manufacturer]" under the agreement "is a fair and reasonable compensation solely for other goods or services that [the generic manufacturer] has promised to provide," or that "[t]he agreement has directly generated procompetitive benefits" that "outweigh [its] anticompetitive effects." § 2(a)(3). As we read the bill, the fact that a settlement **will** have procompetitive effects once the generic enters the market is not sufficient to rebut the antitrust presumption, even if the settlement's net effect is procompetitive in the long run. Furthermore, "[i]n determining whether" a settling party has succeeded in rebutting the statute's threshold presumption of anticompetitiveness, factfinders "shall not presume" "[t]hat [generic] entry into the marketplace could not have occurred until the expiration of the relevant patent[s]" or "that … entry of the [generic] product before the expiration of any patent exclusivity means that the agreement is procompetitive." § 2(b)(1)-(4). Nor may a factfinder "presume" "[t]hat any patent is enforceable." § 2(b)(2).

SB 269 also includes severe penalties. "Any person who violates" the statute and who "received any value due to that violation" "shall forfeit and pay to the State of Connecticut a civil penalty" of "up to 3 times the value received by the party that is reasonably attributable to the violation of this Section, or $20,000,000," "whichever is greater." § 2(e). What is "'[r]easonably attributable to the violation' shall be determined by Connecticut's share of the market for the brand drug at issue in the agreement." § 2(e)(1)(A)(iii). In addition, each "person" who merely "assists in [a] violation" of the statute, but "has *not* received anything of value," is liable to pay "a civil penalty" of **at least** "$20,000,000." § 2(e)(1)(A)(ii). "Any penalty" imposed under SB 269 "shall accrue only to the state treasury and shall be recovered in a civil action brought by the attorney general in its own name." § 2(e)(1)(B). In addition, SB 269 allows the Attorney General to recover additional "relief or damages … other than those that are penalties." § 2(e)(B)(3). Finally, the bill provides that "[e]ach party that violates or assists in the violation of this section shall" additionally "be liable for any damages, penalties, costs, fees, injunctions, or other remedies that may be just and reasonable and available under Connecticut law, including antitrust law in chapter 325D, as applicable." § 2(e)(B)(2).

LEGAL ISSUES

I. SB 269 VIOLATES THE DORMANT COMMERCE CLAUSE.

The United States Constitution provides that "Congress shall have [the] Power … To regulate commerce ... among the several States." Art. I, § 8, cl. 3. This "negative command, known as the dormant Commerce Clause," prohibits States from legislating in ways that regulate or discriminate against interstate commerce. *Okla. Tax Comm'n v. Jefferson Lines, Inc.,* 514 U.S. 175, 179 (1995). "The dormant Commerce Clause 'precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State.'" *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989). A State law that regulates commerce outside the State's borders is "virtually *per se* invalid," *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272

F.3d 104, 108 (2d Cir. 2001), even if the out-of-State commerce the State seeks to regulate "has effects within the State," *Healy*, 491 U.S. at 336 (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality op.)).

Consistent with this virtually per se rule, there is "a long line of cases" both in and out of the Second Circuit "holding that states violate the Commerce Clause by regulating or controlling commerce occurring wholly outside their own borders." *Dean Foods Co. v. Brancel*, 187 F.3d 609, 615 (7th Cir. 1999); *see, e.g.*, *Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608, 612-16 (9th Cir. 2018) (enjoining a California law that purported to "dictate the method by which" medical-waste companies treated medical waste "outside of California," because it "reach[ed] beyond the borders of California [to] control transactions that occur wholly outside of the State"); *Legato Vapors, LLC v. Cook*, 847 F.3d 825, 833 (7th Cir. 2017) (invalidating Indiana law that required "commercial relationships between out-of-state manufacturers and their [out-of-State] employees and contractors" to be conducted consistent with Indiana law if the manufacturers sold products in Indiana); *Am. Beverage Ass'n v. Snyder*, 735 F.3d 362, 366-76 (6th Cir. 2013) (invalidating Michigan law that imposes "unique-to-Michigan mark designation," even though it "does not discriminate against interstate commerce," because it "allows Michigan to dictate where the product can be sold" and thus "control[s] conduct beyond the State of Michigan"); *Am. Booksellers Found. v. Dean*, 342 F.3d 96, 99-104 (2d Cir. 2003) (invalidating Vermont law that prohibited distribution of explicit materials to minors because it regulated what people could distribute in other States and thus "'projected … into other States, and directly regulated commerce therein'" (quoting *Brown-Forman*, 476 U.S. at 584)); *U & I Sanitation v. City of Columbus*, 205 F.3d 1063, 1069 (8th Cir. 2000) (invalidating ordinance on the ground that, if "all cities such as Columbus enacted flow control ordinances like the one at issue here, the interstate market in recyclable materials extracted from solid waste could be substantially diminished or impaired, if not crippled"); *Am. Civil Liberties Union v. Johnson*, 194 F.3d 1149, 1161 (10th Cir. 1999) (invalidating New Mexico law that "attempt[ed] to regulate interstate conduct occurring outside New Mexico's borders"); *see also North Dakota v. Heydinger*, 825 F.3d 912, 921-22 (8th Cir. 2016) (Loken, J.) (invalidating Connecticut laws that "seek to reduce emissions that occur outside Connecticut by prohibiting transactions that originate outside Connecticut," because "their practical effect is to control activities taking place wholly outside Connecticut").

SB 269 violates this foundational rule of constitutional law. Under SB 269, every company that settles a patent suit on terms that Connecticut deems anticompetitive is liable for three times "Connecticut's share of the market for the brand drug at issue in the agreement," and every "person" who "assists" in a "violation" is liable to the tune of **at least** $20 million. And SB 269 cannot reasonably be read to apply only to settlement agreements completed in Connecticut. To be sure, SB 269 contains one geographic reference, which comes in the form of a limitation on penalties to no more than three times Connecticut's market share. But the insertion of this limited state-nexus requirement into the bill's **penalty** provision only underscores that the bill's operative **proscriptions** reach non-Connecticut agreements as long as someone—not even necessarily a settling party—eventually ships at least one dose of a product covered by the settlement into Connecticut. Moreover, the statute's directive to impose penalties of at least $20 million on companies or individuals has no comparable Connecticut-market-share requirement. SB 269 therefore applies to out-of-state settlement agreements regardless of where the transacting parties are located, and regardless of where the medicines covered by the agreement are manufactured or produced. What is more, SB 269 contains the prototypical form of direct regulation, as it imposes "penalties on non-compliant transactions completed wholly out of state." *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1102-03 (9th Cir. 2013).

SB 269 is therefore a textbook violation of the dormant Commerce Clause. Because it regulates commercial activities (*i.e.*, settlement agreements) entirely in other states, it likely will be invalidated without a balancing of local benefit against out-of-state burden. *See Healy*, 491 U.S. at 336. Indeed, although it ultimately avoided invalidating the statute on dubious procedural grounds, the district court in the litigation over California's recently enacted AB 824—on which SB 269 is based, and which is effectively identical to SB 269—agreed that it "would likely violate the Dormant Commerce Clause" "if the Attorney General were to enforce the terms of AB 824 against two out of state parties that entered into a settlement agreement outside of California, having nothing to do with California." Slip op. 8, *Ass'n for Accessible Meds. v. Becerra*, No. 2:19-cv-02281-TLN (E.D. Cal. Dec. 31, 2019).

Furthermore, a proliferation of SB 269–type legislation in other States would wreak havoc on interstate commerce, decimate federal patent rights, and grind to a halt patients' access to lower-priced generic and biosimilar medicines. And, as the Supreme Court has explained, courts in dormant Commerce Clause cases must consider "what effect would arise if not one, but many or every, State adopted similar legislation." *Healy*, 491 U.S. at 336-37. If other States enacted their own versions of SB 269, it would be practically impossible to obtain global peace via settlement, as patent settlements that were lawful under the law of the State in which they were entered (and under federal law) could be subject to crippling and conflicting penalties under the laws of far-flung States. The Constitution exists in no small part because of the framers' "conviction" that curtailing such State overreach was imperative to the long-term survival of the Union. *Okla. Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 180 (1995). Nor is this concern at all far-fetched; SB 269 is modeled on California AB 824, and a number of other States (including Illinois, New York, and Minnesota) currently have similar bills in the legislative pipeline.

In sum, SB 269 is precisely the sort of extraterritorial legislation that is per se unconstitutional under a straightforward application of binding Supreme Court and Second Circuit precedent.

II. SB 269 IS PREEMPTED.

A. SB 269 conflicts with federal patent law.

Under the Supremacy Clause, U.S. Const. Art. VI, cl. 2, State laws that conflict with federal law are preempted. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000).

1. State laws that "upset the careful balance" of a federal regulatory scheme are preempted. *Edgar v. MITE Corp.*, 457 U.S. 624, 634 (1982); *see also Farina v. Nokia, Inc.*, 625 F.3d 97, 123 (3d Cir. 2010) ("The Supreme Court's preemption case law indicates that regulatory situations in which [the government] is required to strike a balance between competing statutory objectives lend themselves to a finding of conflict preemption."). SB 269 upsets the balance Congress struck in federal patent law and the Supreme Court went out of its way to protect in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). It is thus preempted on that basis.

In *Actavis*, the FTC "urge[d the Court] to hold that reverse payment settlement agreements"—*i.e.*, settlements in which the brand-name manufacturer agrees to compensate the generic challenger—"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," and sharply restricted the scope of antitrust review of patent settlements. *Id.* at 159. *Actavis* held that only patent settlements with "unjustified" and "large" "reverse payments" are subject to antitrust scrutiny. *Id.* at 158-59. Ordinary compromise agreements between brands and generics taking "commonplace forms," by contrast, are not "subject to antitrust liability" at all. *Id.* at 152.

Consistent with the federal system's longstanding effort to balance the warring federal interests of competition and innovation, *Actavis* made clear that "patent and antitrust policies are both relevant" to the issue of whether (and if so, under what circumstances) a pharmaceutical patent settlement may be subjected to antitrust scrutiny. *Id.* at 148; *see also id.* ("[C]ourts must 'balance the privileges of [the patent holder] and its licensees under the patent grants with the prohibitions of [antitrust law] against combinations and attempts to monopolize.'" (quoting *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 390-91 (1948))).

Actavis additionally clarified that antitrust scrutiny of patent settlements is consistent with the proper balance between these dueling federal policies only in limited circumstances. In particular, a patent settlement may give rise to antitrust liability under *Actavis* only when it contains a "large and unjustified" payment from the brand-name drug company to the generic—and, even then, a settlement that includes a large reverse payment may be scrutinized only under the rule of reason, which requires meaningful proof that the settlement is anticompetitive, rather than under a "quick look" approach that presumes anticompetitiveness and shifts the burden to settling parties to defend it. *Id.* at 158-59.

As currently drafted, SB 269 is fundamentally inconsistent with the carefully balanced federal regime set forth in *Actavis*. SB 269 departs from *Actavis* in five key ways:

- SB 269 erects a threshold presumption that reverse-payment patent settlements are anticompetitive. That conflicts with *Actavis*, which rejected precisely such a presumption. 570 U.S. at 158-59 ("The FTC urges us to hold that reverse payment settlement agreements are presumptively unlawful…. We decline to do so.").

- SB 269 abandons the rule of reason in favor of a "quick look" approach. That also conflicts with *Actavis*, which rejected a "quick look" approach because such an approach is insufficiently solicitous of patent interests. *Id.* at 148, 159.

- SB 269 places the ultimate burden on the defendant. That too conflicts with *Actavis*, which held that reverse-payment settlements may be scrutinized only under the rule of reason, under which the ultimate burden always lays with the antitrust challenger. *Id.* at 158-59.

- SB 269 defines reverse payments ("anything of value") to include "an exclusive license." In contrast, *Actavis* held that only "unjustified" and "large" "reverse payments" are subject to antitrust scrutiny, *Id.* at 158-59, and made clear that ordinary compromise agreements taking "commonplace forms," such as those expressly authorized by the Patent Act, are not "subject to antitrust liability," *id.* at 152.

- SB 269 allows brands to offer generics compensation for saved litigation expenses only if the "saved litigation expenses [are] reflected in budgets that [generic manufacturer] documented and adopted at least six months before the settlement," and, even then, only up to $7.5 million. *Actavis* imposed no such cap or documentation requirement. In fact, *Actavis* recognized that "[w]here a reverse payment reflects traditional settlement considerations, such as avoided litigation costs …, there is not [a] concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." *Id.* at 156.

2. Beyond these conflicts with *Actavis*, SB 269 also conflicts directly with provisions of the federal Patent Act.

First, whereas the Patent Act instructs that "[a] patent shall be presumed valid" and enforceable, 35 U.S.C. § 282(a), SB 269 prohibits the factfinder from presuming that "any patent" at issue in the underlying litigation "is enforceable," § 2(b)(2). SB 269 thus diminishes the value of a federally conferred patent. And, although States are free to enact antitrust laws that differ from federal antitrust law, they cannot diminish the protection accorded patent holders. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989) ("[S]tate regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws."); *see, e.g.*, *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 348 (2001) (preempting State law where "allowing fraud-on-the-FDA claims under state" law could "skew[]" the "delicate balance of statutory objectives").

Second, whereas the Patent Act confers the right to grant exclusive licenses on patent holders such as brand-name drug companies, *see* 35 U.S.C. § 261, SB 269 defines payment to "includ[e]" "an exclusive license," § 2(a)(1)(A). This latter conflict is particularly stark, as even the FTC has affirmed that settlements containing exclusive licenses and early-but-not-immediate entry are generally procompetitive. *See, e.g.*, Br. of FTC as Amicus Curiae, *Am. Sales Co. v. Warner-Chilcott Co., LLC*, Nos. 15-1250 & 14-2071, 2015 WL 3957874, at *29 (1st Cir. June 16, 2015).

In sum, SB 269 is likely preempted, because it appears to upset the delicate federal balance between patent and antitrust, and directly conflicts with the Patent Act as well.

B. SB 269 poses an obstacle to the operation of the Hatch-Waxman Act.

Under a separate variant of conflict preemption, "a state law is preempted where it 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Arizona v. United States*, 567 U.S. 387, 406 (2012) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)); *accord, e.g.*, *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000); *see Wyeth v. Levine*, 555 U.S. 555, 565 (2009) ("[T]he purpose of Congress is the ultimate touchstone in every preemption case." (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996))). SB 269 stands as an obstacle to the basic objectives of the federal regulatory regime Congress put in place to help speed generic medicines onto the market.

The Food, Drug and Cosmetic Act bars manufacturers from marketing a new brand-name drug unless the FDA approves a "new drug application" (NDA) for it. 21 U.S.C. § 355(a). An NDA must show that the drug is safe and effective, *id.* § 355(d), which entails "an extensive" and expensive "series of safety and effectiveness trials," *Guilbeau v. Pfizer Inc.*, 880 F.3d 304, 307 (7th Cir. 2018). However, under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Act, the process for new generic drugs is "shorter and less onerous." *Guilbeau*, 880 F.3d at 307. If the prospective generic drug is "the same as" an existing drug already on the market, a manufacturer can obtain approval through the abbreviated new drug application (ANDA) process. *See* 21 U.S.C. § 355(j)(2)(A). "The ANDA process requires proof that the drug in question has the same active ingredients, effects, and labeling as a predecessor drug that the FDA has already approved." *Guilbeau*, 880 F.3d at 307. But, because the ANDA process allows manufacturers to piggy-back on already-filed NDAs, it is much less costly, which allows generic drugs to come onto market at a fraction of the price of otherwise-equivalent brand-name drugs.

Because generic drugs are considerably less expensive, Congress's overriding purpose in enacting the Hatch-Waxman Act was "to get 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) (citation omitted); *see* H.R. Rep. No. 98-857, pt. 1, at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647 (Congress intended Hatch-Waxman to "make available more low cost generic drugs"). Given extant patent law, however, the Hatch-Waxman Act could not simply create an expedited pathway for generic manufacturers to bring their medicines to market without giving brand-name companies a say. In light of federal patent protections, the expedited pathway the Hatch-Waxman Act created generally leads brand-name drug companies to sue generic manufacturers for patent infringement. *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405-07 (2012).

Those lawsuits are extremely expensive. "[T]he cost of litigation in this specific context—a generic challenging a brand name pharmaceutical patent—was about $10 million per suit" a decade ago, *Actavis*, 570 U.S. at 170 (Roberts, C.J., dissenting), and the costs have only increased since then, Malathi Nayak, *Costs Soar for Trade Secrets, Pharma Patent Suits, Survey Finds*, Bloomberg Law (Sep. 10, 2019) (cost rose 67% between 2015 and 2019), https://bit.ly/2ki106U. And, unlike their brand-name counterparts, generic manufacturers typically operate on thin margins. That is why Congress made the first filer of a certain type of ANDA eligible for a 180-day exclusivity period. 21 U.S.C. § 355(j)(2)(A)(vii)(IV), (j)(5)(B)(iv); *see Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1318 (D.C. Cir. 2010) (noting that Congress recognized that, in light of the high costs of patent litigation, generics are unlikely to take steps to challenge patents without a "reward" for "stick[ing] out their necks"). But of course there is no guarantee that challenging a patent will be successful and thus pave the way for market entry. To the contrary, when these types of suits are litigated to judgment, the generic manufacturer prevails over the brand-name drug company less than half the time. *See* SBC Capital Mkts., *Pharmaceuticals: Analyzing Litigation Success Rates* 4 (Jan. 15, 2010), https://bit.ly/2LPXaga; Br. for the Generic Pharm. Ass'n as *Amicus Curiae* Supporting Resps. 16-17, *FTC v. Actavis, Inc.*, No. 12-451, 2013 WL 769341 (U.S. Feb. 28, 2013) (same for secondary patents).

As a result, patent settlements are often necessary for generic manufacturers to bring their medicines onto the market in a timely manner. Indeed, patent settlements are often the only way generic manufacturers can cut through brand-name companies' patent portfolios. Brand-name drug companies often file "follow-on" patent applications, which extend the exclusivity period protecting their products multiple additional years, and

accordingly raise the cost of patent litigation many times over. Marshall Leaffer, *Patent Misuse and Innovation*, 10 J. High Tech. L. 142, 163 (2010). Given those patent estates, a generic medicine often cannot get onto the market through the Hatch-Waxman mechanism without going through potentially several discrete patent infringement lawsuits, each of which may cost millions of dollars and may take multiple years from start to finish if litigated to judgment. That is why, in *Actavis*, the Supreme Court made clear that even so-called "reverse payment" patent settlements typically "bring about competition …to the consumer's benefit." 570 U.S. at 154. Patent settlements are often the only way that generic manufacturers can get their products onto the market anytime soon.

SB 269 throws a wrench into the carefully calibrated federal regime. The bill currently defines **any form of exclusive license**—even a time-limited one that operates only against other generics for a few months—to constitute "a[ ]thing of value" that triggers the statute's threshold presumption of anticompetitiveness. *See* § 2(a)(1)(A). As a result, the statute renders presumptively unlawful even run-of-the-mill pharmaceutical patent settlements. Particularly given the penalties it imposes, the bill's immediate effect would therefore be to scuttle patent settlements now in the works and on the near-horizon. Given the ruinous financial consequences that could befall an individual for simply being a cog in a settlement that turns out to violate SB 269, common sense dictates that regulated entities will steer clear of settling patent disputes anywhere in the country on terms that might even arguably come within the statute's terms.

And, by rendering pharmaceutical settlement agreements prohibitively risky for generic manufacturers (and the individual persons who work for them), SB 269's ultimate effect will be to dissuade generic manufacturers from filing ANDAs challenging patents and trying to enter the market prior to patent expiry altogether, given that such filings almost inevitably "provok[e]" costly patent-infringement "litigation." *Caraco*, 566 U.S. at 407. That is fundamentally at odds with the Hatch-Waxman Act. The Hatch-Waxman Act not only is premised on the notion that, because patent-infringement litigation is extremely expensive, patent settlements often are necessary for, but is designed to, get generic medicines onto the market in a timely manner.[2]

Because it will make it more difficult for generic manufacturers to bring their lower-priced products onto the market, SB 269 stands as an obstacle to the fundamental objectives of the Hatch-Waxman Act, and likely is preempted on this ground as well.

C. SB 269 conflicts with the Biologics Price Competition and Innovation Act of 2009.

Much like the Hatch-Waxman Act did with generics, the Biologics Price Competition and Innovation Act of 2009 (BPCIA), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010) (codified as amended at 42 U.S.C. § 262, 35 U.S.C. § 271(e), 28 U.S.C. § 2201(b), 21 U.S.C. § 355 *et seq.*), established an abbreviated pathway for regulatory approval of follow-on biological products that are "highly similar" to a previously approved biologic. 124 Stat. at 804, 815; *see supra* note 1. Specifically, the BPCIA established a biosimilar patent dispute resolution regime that "allow[s] infringement suits to begin based on the filing of a biosimilar application prior to FDA approval and prior to marketing of the biological product." *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1321 (Fed. Cir. 2017); *see* 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6).

As with the parallel type of patent litigation under the Hatch-Waxman Act, this type of patent litigation is extremely expensive. As a result, settlement is equally (if not more) likely in biologic/biosimilar cases than in brand/generic cases. Because SB 269 frustrates patent settlements in biologic/biosimilar cases just as in brand/generic cases, it likewise frustrates, and stands as an obstacle to, a core objective of the BPCIA—namely, getting low-cost biologics on the market.

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[2] That premise has largely proven correct in practice. Much of the savings that generics have unlocked would not have been possible if the option of settling patent disputes had not been on the table. *See* IMS Inst. for Healthcare Informatics, *Impact of Patent Settlements on Drug Costs: Estimate of Savings* (2013) (patent settlements moved up generic entry by an average of 81 months, or 6.75 years), https://bit.ly/2pC5uaA.

SB 269's application to settlements arising out of biologic/biosimilar cases is also likely field preempted. Under field preemption, "state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively." *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Courts "may infer such a congressional intent from a 'scheme of federal regulation … so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it,' or where an Act of Congress 'touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Amgen*, 877 F.3d at 1326 (alterations in original) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Applying that analysis, the Federal Circuit recently held that the BPCIA has field-preemptive effect, because its "comprehensive, carefully calibrated 'scheme of federal regulation … [is] so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Id.* at 1328 (quoting *Rice*, 331 U.S. at 230).

"Where Congress occupies an entire field … even complementary state regulation is impermissible." *Arizona v. United States*, 567 U.S. 387, 401 (2012). Thus, SB 269 is preempted to the extent it applies to settlements arising out of biologic/biosimilar patent litigation.

III. SB 269 LIKELY VIOLATES THE EXCESSIVE FINES CLAUSE.

SB 269 appears to violate the Eighth Amendment's Excessive Fines Clause, U.S. Const. amend. VIII ("Excessive bail shall not be required, nor excessive fines imposed…."). *See Timbs v. Indiana*, 139 S. Ct. 682, 686-87 (2019) (incorporating Excessive Fines Clause against States).

First, SB 269's penalty provision constitutes a "fine" within the meaning of the Excessive Fines Clause. The Supreme Court has defined "fines" subject to the Clause as "cash [or] in-kind payment[s] imposed by and payable to the government." *Dep't of Hous. & USBan Dev. v. Rucker*, 535 U.S. 125, 136 n.6 (2002). SB 269 satisfies that requirement. The bill not only refers to the exaction it imposes as a "penalty," but limits collection of that "penalty" to "the attorney general." § 2(e)(1)(B). The "penalty" also must be "sufficient to deter violations of this section," § 2(e)(1)(A), which underscores that it is not merely compensatory. *See WCI, Inc. v. Ohio Dep't of Pub. Safety*, 774 F. App'x 959, 967 (6th Cir. 2019). In short, the payment is imposed by and payable to the government, and is thus is a fine for purposes of the Excessive Fines Clause.

The bill's penalty provision also likely violates the Excessive Fines Clause as applied to individuals. A penalty "violates the Excessive Fines clause if it is grossly disproportional to the gravity of a defendant's offense." *United States v. Bajakajian*, 524 U.S. 321, 328-34 (1998). The minimum penalty that may be imposed under SB 269 is $20 million. § 2(e)(1)(A)(ii). And, as the district court in the California litigation recognized when construing language identical to SB 269's, the statute on its face authorizes the imposition of $20-million-or-more penalties even against individuals who merely "assist" with a settlement later deemed a violation—down to the "junior associate or legal secretary working at the law firm representing one of the settling parties." *Becerra* slip op. 16.

The "touchstone of the constitutional inquiry under the Excessive Fines Clause" is "proportionality." *Bajakajian*, 524 U.S. at 334. There is no circumstance in which a penalty of *at least* $20 million is remotely proportional to the "offense" of assisting with a patent settlement. Assisting with parties entering into a settlement agreement to resolve a patent dispute is not the type of activity that justifies large (or any) penalties. *Actavis* itself expressly "recognize[d] the value of settlements" in the pharmaceutical context. 570 U.S. at 153-54 ("[S]ettlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit"). That is particularly true given that most patent settlements that SB 269 reaches are entirely lawful under federal law. As noted, *Actavis* held that only "unjustified" and "large" "reverse payments" are subject to antitrust scrutiny, *id.* at 158-59, and made clear that ordinary compromise agreements taking "commonplace forms," such as those expressly authorized by the Patent Act, are not "subject to antitrust liability" at all, *id.* at 152. SB 269, in contrast, defines reverse payments ("anything of value") to include "an exclusive license," § 2(a)(1)(A), which is a commonplace settlement term. Individuals are thus subject to multimillion-dollar penalties under SB 269 for assisting in ordinary business conduct that is perfectly lawful under federal law. That is unconstitutionally excessive under any scenario, as the district court in the California litigation

recognized. *See Becerra* slip op. 16 (agreeing that California's identical, $20-million minimum fine likely violates the Eighth Amendment Excessive Fines Clause "as applied to individuals").

IV. SB 269 IS CONTRARY TO DUE PROCESS.

SB 269 appears to erect a presumption that, in practice, "operates to deny a fair opportunity to repel it," in violation of the Due Process Clause. *W. & Atl. R.R. v. Henderson*, 279 U.S. 639, 642 (1929).

The bill "presume[s]" that a pharmaceutical patent settlement has "anticompetitive effects and [is] a violation of this Section" if, as part of the agreement, a generic manufacturer (1) "receives anything of value" and (2) "agrees to limit or forego research, development, manufacturing, marketing, or sales of [its] product for any period of time." § 2(a)(1)(A)-(B). Given the statute's broad definition of "value," which includes even an ordinary "exclusive license," § 2(a)(1)(A), that initial presumption covers many (if not most) patent settlements.

To be sure, a defendant nominally may rebut the presumption of anticompetitiveness. But if the evidence is in equipoise, the defendant loses, and "[e]ach person that violate[d]" the statute (or merely "assist[ed] in the violation") is liable for "a civil penalty" of no less than $20 million. § 2(e)(1)(A)(ii). And the provisions setting forth precisely how a defendant can rebut that presumption in practice erect a byzantine structure that appears extremely difficult, if not impossible, to rebut.

To rebut the presumption, a defendant must prove by a preponderance of the evidence either that "[t]he value received by the [generic manufacturer]" under the agreement "is a fair and reasonable compensation solely for other goods or services that [the generic manufacturer] has promised to provide," or that "[t]he agreement has directly generated procompetitive benefits" that "outweigh [its] anticompetitive effects." § 2(a)(3)(A)-(B). And, in evaluating whether a defendant has made that showing, the factfinder is foSBidden (in conflict with federal patent law) from presuming that a patent "is enforceable," that generic entry "could not have occurred until the expiration of the relevant patent exclusivity," or that "the agreement's provision for entry of the [generic] product before the expiration of any patent exclusivity means that the agreement is procompetitive." § 2(b).

Furthermore, as the district court in the California litigation recognized when addressing identical text, even if a defendant proves both that a settlement the statute reaches "**will** have procompetitive effects" once the generic product enters the market, **and** that those long-term benefits will outweigh the short-term consequences of maintaining the status quo (in which the brand's patents are enforceable, and thus block immediate generic entry), that **still** "is not sufficient to rebut the antitrust presumption" the bill erects. *Becerra* slip op. 23 (emphasis in original). As a result, the bill appears likely to be unconstitutional, as States may not impose liability "without first providing [defendants] with 'an opportunity to present every available defense.'" *Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007) (quoting *Lindsey v. Normet*, 405 U.S. 56, 66 (1972)).

Sincerely,

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