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Appeal Filed by AstraZeneca Pharmaceuticals, LP v. Lopez, 9th Cir., February 27, 2026

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United States District Court, D. Hawai'i.

ASTRAZENECA PHARMACEUTICALS **LP**, Plaintiff,
v.
Anne E. **LOPEZ**, Attorney General of the State of Hawai'i, Defendant.

Civil No. 25-00369 MWJS-WRP
|
Signed February 23, 2026

Attorneys and Law Firms

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ORDER DENYING MOTION FOR A PRELIMINARY INJUNCTION

Micah W.J. Smith, United States District Judge

INTRODUCTION

***1** Plaintiff **AstraZeneca** Pharmaceuticals **LP** moves for a preliminary injunction against enforcement of Hawai'i Act 143, a state statute that prohibits drug manufacturers from imposing certain restrictions on the sale of discounted drugs within a federal pricing program. **AstraZeneca** argues that Act 143 is preempted by federal law because it conflicts with the objectives of the federal program and, as applied to **AstraZeneca's** patented products, conflicts with federal patent law.

A preliminary injunction is "an extraordinary and drastic remedy," ***Lopez*** *v. Brewer*, 680 F.3d 1068, 1072 (9th Cir. 2012) (quoting *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam)), and is available only when a party shows a likelihood of success on the merits, or at least strong questions going to the merits. Because **AstraZeneca** has not made that showing, at least at this early stage in the case, its motion is DENIED.

BACKGROUND

A. Factual Background

In 1992, Congress created the Section 340B Drug Pricing Program under the Public Health Service Act. 42 U.S.C. § 256b. The program ties access to lucrative federal drug reimbursement markets to a pricing commitment: drug manufacturers that want their products covered under Medicaid and Medicare Part B must enter into an agreement with the Secretary of the U.S. Department of Health and Human Services (HHS) and comply with Section 340B's requirements, including its drug pricing requirement. *Id.* § 256b(a)(1). Under this drug pricing requirement, manufacturers must "offer" their "covered outpatient drugs" to a limited set of qualifying providers for purchase at or below a statutory ceiling price. *Id.* Those qualifying providers —known as "covered entities"—then "benefit through insurance reimbursements that exceed the marked-down cost of the drugs." *Novartis* ***Pharms.*** *Corp. v. Johnson*, 102 F.4th 452, 455 (D.C. Cir. 2024).

Section 340B contains several intersecting provisions that define the scope and mechanics of the drug pricing requirement. It sets out how ceiling prices are calculated, § 256b(a)(2); identifies what constitutes a covered outpatient drug, §§ 256b(a)(3), (b)(2); and specifies which categories of providers qualify as covered entities, § 256b(a)(4). Covered entities are generally providers that serve underserved communities, including patients who face financial constraints or limited access to care. *See Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113 (2011) (explaining that covered entities "include public hospitals and community health centers, many of them providers of safety-net services to the poor"). By reducing acquisition costs for these providers, the Section 340B program is intended to help them maintain and expand services and improve patient access to medications. But there is no requirement that the covered entities send those savings along to patients.

Administration of the Section 340B program rests with HHS, which acts through the Health Resources and Services Administration (HRSA). *See Astra*, 563 U.S. at 113. The program includes various guardrails to ensure the drug discounts are not abused. Covered entities may not obtain a Section 340B discount for drugs that are also subject to a Medicaid rebate—sometimes described as the prohibition on duplicate discounts. 42 U.S.C. § 256b(a)(5)(A). They also may not transfer discounted drugs to individuals who are not their patients—described as the prohibition on diversion. *Id*. § 256b(a)(5)(B). To support these limits, covered entities must make records available for audits conducted by the Secretary and by manufacturers under procedures the Secretary establishes. *Id*. § 256b(a)(5)(C). If diversion or duplicate discounts occur, the statute authorizes the manufacturer to recoup the difference and includes additional consequences for covered entities. *Id*. §§ 256b(a)(5)(D), (d)(2)(B)(v). The statute also provides for penalties when manufacturers charge more than the ceiling price for a drug. *Id*. § 256b(d)(1)(B)(vi). But so long as covered entities do not engage in diversion or seek duplicate discounts, Section 340B entitles them to obtain discounted drugs for every single one of their qualifying patients, without limit.

***2** Although Congress enacted these specific statutory guardrails, and entrusted HHS with their enforcement, Congress did not grant HHS broad authority to regulate every aspect of the program through rulemaking. *See, e.g.*, *American Hospital Association v. HHS*, No. 4:20-CV-08806-YGR, 2021 WL 616323, at *7 (N.D. Cal. Feb. 17, 2021) ("Congress... has not given HHS ... broad rulemaking authority."). Instead, the agency's rulemaking authority is limited to specific subjects, including the administrative dispute resolution (ADR) process, drug-pricing methodology, and monetary sanctions for violations. *Pharmaceutical Research & Manufacturers of America v. HHS*, 43 F. Supp. 3d 28, 41-45 (D. D.C. 2014).

And while manufacturers participating in the Section 340B program are required to "offer" their covered outpatient drugs to covered entities "for purchase" at or below statutory ceiling prices, Congress enacted no express language prohibiting manufacturers from imposing onerous delivery conditions that might effectively nullify the discounted offers they are required to make. *See Novartis*, 102 F.4th at 462 (noting the concern that a manufacturer could theoretically "require that a covered entity pick up its orders one pill at a time"). Concerned about that risk—and in spite of the fact that it lacked regulatory authority over the subject matter of delivery conditions—HRSA issued guidance in 1994 opining that manufacturers may not "single out covered entities" for "restrictive conditions" such as "minimum purchase amounts." *Id.* at 456 (quoting 1994 Guidance, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994)).

In 1996, HRSA provided further guidance. Recognizing that "many covered entities use outside pharmacies to distribute drugs to their patients," HRSA opined that covered entities without in-house pharmacies were authorized to contract with an outside pharmacy—that is, a "contract" pharmacy—to dispense drugs at a single location. *Id.* at 457 (citing 1996 Guidance, 61 Fed. Reg. at 43,549–50). HRSA acknowledged that Section 340B was "silent as to permissible drug distribution systems," but explained that it sought to fill the "gaps in the legislation" and thereby "move the program forward." *Id.*; *see also id.* at 460 (noting HRSA's acknowledgment that Section 340B is "silent about delivery conditions").

For the next fourteen years, Section 340B program participants followed HRSA's guidance, and covered entities generally relied on a small number of pharmacies to dispense discounted drugs. *See id.* at 456-57. That practice changed after HRSA issued new guidance in 2010 taking the position that covered entities could "engage an unlimited number of outside pharmacies ... regardless of whether the entities have in-house pharmacies" to reach areas and patients they could not otherwise. *Id*. at 457. In the wake of that guidance, the number of covered entities "participating in the program increased from about 9,700 to 13,000 between 2010 and 2019." *Id*. Contract pharmacy arrangements, too, increased substantially, as many covered entities entered into agreements with large numbers of pharmacies across broad geographic areas. As contract pharmacy use expanded, a growing share of Section 340B drugs came to be dispensed through those pharmacies.

During the same period, many covered entities and pharmacies adopted inventory and accounting practices that differ from traditional segregated drug inventories. The most common of these is now the "replenishment" model; it is used by covered entities across the United States, and limited expedited discovery conducted in connection with the pending motion reveals that it is in common use in Hawai'i. Under the replenishment model, a pharmacy dispenses drugs from its general inventory at the point of sale. After dispensing occurs, claims data are reviewed to determine which transactions are eligible for Section 340B pricing—

often by third-party administrators who have a monetary incentive to declare as many transactions to be eligible for the Section 340B discount as possible. For each transaction found to be eligible, the covered entity purchases replacement drugs at the discounted price through its wholesaler to replenish the inventory previously used for eligible patients.

3** These shifts changed how the program operated in practice and eventually prompted disagreement among manufacturers, covered entities, and HRSA regulators. Manufacturers expressed concern that the widespread use of contract pharmacies made it more difficult to monitor compliance with statutory limits, including the prohibitions on diversion and duplicate discounts. *Id*. at 458. Covered entities and pharmacies, by contrast, emphasized that contract pharmacies were often necessary to ensure that patients—particularly those living far from hospital facilities or in underserved communities—could obtain prescribed medications. Beginning in 2020, several pharmaceutical manufacturers adopted policies limiting the circumstances under which they would make discounted drugs available for distribution through contract pharmacies. *See id*. ("In 2020, [Novartis Pharmaceuticals Corporation and United Therapeutics Corporation] began to limit the number and kinds of contract pharmacies to which they would ship orders."); *see also* ***AstraZeneca *Pharmaceuticals* ***LP*** *v. Becerra*, 543 F. Supp. 3d 47, 52 (describing **AstraZeneca's** 2020 policy limiting the distribution of 340B drugs). The details of these policies varied among manufacturers, but commonly included limits on the number of contract pharmacies eligible for discounted pricing, requirements related to claims data sharing, or conditions tied to reporting and oversight. Manufacturers characterized these policies as efforts to reduce the risk of diversion and duplicate discounts. Covered entities and pharmacies responded that the policies impeded their ability to serve patients and restricted access to discounts that the 340B program was intended to provide.

In response to manufacturer restrictions, in December 2020, the HHS and HRSA took the position that the Section 340B statute requires manufacturers to make discounted drugs available not only to covered entities, but also through contract pharmacies designated as agents by those entities. HRSA began taking steps to challenge manufacturer policies restricting contract pharmacy use, while some pharmaceutical companies sued to enjoin HRSA's policy mandating sales to contract pharmacies. *See, e.g.*, ***AstraZeneca*** *Pharmaceuticals* ***LP*** *v. Becerra*, 543 F. Supp. 3d at 53. Then, in May 2021, the agency sent violation letters to several manufacturers stating that limitations on contract pharmacies and claims data requirements were inconsistent with the Section 340B program. HRSA directed manufacturers to provide discounted drugs to covered entities without the conditions imposed by those policies, including by making drugs available for delivery to pharmacies designated by covered entities. Manufacturers responded by filing lawsuits in multiple federal courts, seeking to invalidate the agency's violation letters.

Most district courts that addressed the validity of HRSA's enforcement efforts through the violation letters concluded that the violation letters could not stand; two courts of appeals affirmed that conclusion. In *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696 (3d Cir. 2023), the Third Circuit held that the Section 340B statute does not require manufacturers to provide discounted drugs through contract pharmacies, and that HRSA lacked broad regulatory authority to impose such a requirement. The court emphasized that the statute focuses on the price manufacturers must offer to covered entities and does not prescribe the manner or location of drug delivery. *Id*. at 703–04. Indeed, the Third Circuit held that the statute was "silent about delivery." *Id*. at 703. On that basis, the court determined that the agency had not demonstrated that manufacturer policies restricting contract pharmacy arrangements violated the statute, and on that basis enjoined "HHS from enforcing against them its reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies." *Id*. at 706.

The D.C. Circuit reached a similar conclusion in favor of the manufacturers in *Novartis*, 102 F.4th 452. There, the court explained that the statute obligates manufacturers to offer drugs at or below a specified price but is "silent about delivery conditions." *Id*. at 460. The court reasoned that, absent statutory direction, manufacturers retain discretion over distribution terms, subject to the limitation that such terms cannot effectively circumvent the statutory pricing requirement. *Id*. at 462–63. Because the manufacturers' policies at issue did not, on their face, undermine the statutory ceiling price or the obligation to make a bona fide offer, the court concluded that HRSA had exceeded its authority in issuing the violation letters. *Id*. The court, however, did not "foreclose the possibility that other, more onerous conditions might violate the statute," or that even the conditions at issue might be unlawful "as applied in particular circumstances." *Id*. at 464.

***4** Together, these decisions stand for the proposition that federal law does not require manufacturers to allow covered entities to use unlimited contract pharmacies in all cases and all places. But neither court had occasion to consider whether federal law might indeed require manufacturers to allow the use of unlimited or at least multiple contract pharmacies "as applied in particular circumstances." *Id.* Nor did either court definitively resolve how strictly or deferentially federal law might require a court to scrutinize, on an as-applied basis, restrictions on the use of contract pharmacies or other delivery conditions that might impair a covered entity's ability to avail itself of its right to discounted Section 340B drugs for all of its eligible patients.

B. Hawai'i Act 143

Many states have, however, evidently interpreted the Third Circuit and D.C. Circuit decisions as signaling that federal law requires little scrutiny of delivery restrictions, whether facially or as applied. Operating on that assumption, states have adopted legislation to ensure that manufacturers cannot, in the face of federal law's assumed silence on delivery conditions, limit or prohibit the use of contract pharmacies by covered entities. Joining this wave of state legislation, the Hawai'i Legislature enacted Act 143 in 2025, which became effective on July 1, 2025. Dkt. No. 43, at PageID.462.

The Hawai'i Legislature adopted Act 143 in the context of ongoing disputes over manufacturer restrictions on contract pharmacy arrangements and concerns about access to medications for patients served by covered entities in Hawai'i. *See* Dkt. No. 43-3, at PageID.500-01 ("The legislature additionally finds that contract pharmacies are crucial in Hawaii, where geographic barriers make access to health care difficult for many residents."). Covered entities in the state—including hospitals and clinics that serve rural areas—had increasingly relied on contract pharmacies to ensure that patients could obtain prescribed medications without significant logistical barriers. *Id*.

But finding their use of contract pharmacies restricted by manufacturers, hospitals experienced "reduced savings, which could result in cutbacks to essential health care programs." Dkt. No. 43-3, at PageID.501. Act 143 therefore addresses the acquisition and delivery of drugs purchased under the Section 340B program and the role of contract pharmacies in that process. To that end, the provision at issue in this case prohibits manufacturers from interfering with the acquisition or delivery of Section 340B drugs by covered entities and their contract pharmacies. Specifically, Act 143 provides that a manufacturer, or its agent or affiliate, may not "deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or shipping or delivery of a 340B drug to," a pharmacy that is under contract with a covered entity and authorized to dispense Section 340B drugs on its behalf, unless such receipt is prohibited by HHS. *Id*. at PageID.501-02.

C. Procedural History

AstraZeneca responded with this lawsuit, in which it challenges Act 143 on four grounds: that Act 143 is preempted by Section 340B and by federal patent law, and that the Act violates both the Contracts Clause and the Takings Clause. **AstraZeneca's** motion for a preliminary injunction, however, is limited to its federal preemption claims. The State, meanwhile, has moved to dismiss the complaint in its entirety. With the parties' stipulation, the court permitted limited expedited discovery relevant to the preliminary injunction motion and invited supplemental briefing based on that record.

The court held a hearing on the motion for preliminary injunction on February 9, 2026, at which it heard the testimony of Chris Mancill, Senior Vice President & Head of U.S. Market Access at **AstraZeneca**, and heard argument from counsel. Dkt. No. 98. Based on the court's evaluation of his demeanor, as well as the consistency of his testimony with other evidence available in the record, the court concludes that Mr. Mancill testified truthfully at the hearing. The court also commends all counsel for submitting helpful written briefs and presenting exceptionally effective oral argument at the hearing.

***5** By this order, the court now resolves the motion for a preliminary injunction. The State's pending motion to dismiss, on which argument has not been heard, will be resolved by separate order.

MOTION FOR A PRELIMINARY INJUNCTION

As noted, a preliminary injunction is "an extraordinary and drastic remedy, one that should not be granted unless the movant, by a clear showing, carries the burden of persuasion." ***Lopez***, 680 F.3d at 1072 (quoting *Mazurek*, 520 U.S. at 972). To obtain this extraordinary relief, a plaintiff generally must demonstrate "(1) a likelihood of success on the merits, (2) a likelihood of irreparable harm in the absence of preliminary

relief, (3) that the balance of equities favors of the plaintiff, and (4) that an injunction is in the public interest." *Geo Grp., Inc. v. Newsom*, 50 F.4th 745, 753 (9th Cir. 2022) (en banc) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)).

Among these factors, likelihood of success on the merits "is the most important" and "is a threshold inquiry." *Garcia v. Google, Inc.*, 786 F.3d 733, 740 (9th Cir. 2015) (en banc). So when "a plaintiff [fails] to show the likelihood of success on the merits," *Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937, 944 (9th Cir. 2013)—or at least "serious questions going to the merits," *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134–35 (9th Cir. 2011)—the court need not reach the remaining factors. *See Disney Enters., Inc. v. VidAngel, Inc.*, 869 F.3d 848, 856 (9th Cir. 2017).

DISCUSSION

AstraZeneca seeks to preliminarily enjoin Act 143 on the grounds that it is preempted by federal law. The U.S. Constitution's Supremacy Clause indeed authorizes Congress "to preempt state law," *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000), and Congress often expressly provides for preemption in the text of its statutes. But even "without an express provision," courts have found implied preemption in two circumstances. *Id.* The first is field preemption: "When Congress intends federal law to 'occupy the field,' state law in that area is preempted." *Id.* The other is conflict preemption: "even if Congress has not occupied the field, state law is naturally preempted to the extent of any conflict with a federal statute." *Id.*

There are, in turn, two forms of conflict preemption. The first arises when it is impossible for a private party to comply with the mandates of overlapping federal and state law. *Id.* The second concerns situations in which a state law "creates an unacceptable 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " *Wyeth v. Levine*, 555 U.S. 555, 563-64 (2009) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

AstraZeneca relies here on that latter form of conflict preemption—"obstacle" or "purposes and objectives" preemption. It bears emphasizing that this is not an easy doctrine to apply. As the Ninth Circuit has recognized, "deciding just when a state law is 'contrary' to a federal law is often difficult," and "there is an *ad hoc* sense to many of the cases." *Nexus **Pharms**., Inc. v. Central Admixture **Pharm**. Serv's, Inc.*, 48 F.4th 1040, 1045 (9th Cir. 2022) (cleaned up). And given that the doctrine departs from the enacted text of federal legislation, it has come under criticism. *See, e.g.*, *Wyeth*, 555 U.S. at 604 (Thomas, J., concurring in the judgment) (observing that " 'purposes and objectives' preemption jurisprudence" can "lead[ ] to decisions giving improperly broad pre-emptive effect to judicially manufactured policies, rather than to the statutory text enacted by Congress pursuant to the Constitution").

***6** But while the assessment of obstacle preemption "is a matter of judgment," the court's exercise of that judgment must be "informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Crosby*, 530 U.S. at 373. Given these standards, an evaluation of the precise nuances of federal law can have a significant effect on the proper outcome.

AstraZeneca argues that Act 143 must yield because it creates an unacceptable obstacle for two sets of federal laws: the Section 340B program itself, as well as federal law patent law. In addition to defending each of these specific preemption theories, **AstraZeneca** makes two broad threshold arguments in support of both theories: first, that "Act 143 regulates drug *pricing*, not distribution," Dkt. No. 21-1, at PageID.107 (emphasis in original); and second, that "no presumption against preemption of state law is appropriate here," *id.* at PageID.105. Because they inform the proper analysis of **AstraZeneca's** specific preemption theories, the court begins by taking up these more general threshold arguments.

A. Act 143 Regulates Delivery Conditions, Rather than Price

One of **AstraZeneca's** threshold arguments—which it advances in support of both of its preemption theories—is that Act 143 does not merely regulate delivery conditions, but instead impermissibly regulates pricing of drugs. As **AstraZeneca** puts it, "pricing is the only thing distinguishing a sale that complies with Act 143 from a sale that violates the law," and a statute that "forbids charging too much is a law that regulates pricing." Dkt. No. 21-1 at PageID.108–09.

This threshold distinction between price regulation and delivery regulation matters because **AstraZeneca's** preemption theories rely heavily on it. *See, e.g.*, Dkt. No. 76, at PageID.734-44. As will become clearer below, if Act

143 is understood as a price regulation, **AstraZeneca** has a considerably stronger argument that both Section 340B and patent law preempt Act 143. That is because these federal laws carefully and thoroughly regulate pricing; a state law purporting to regulate price would be more likely to impede Congress' careful price-related balancing. If, however, Act 143 is understood as regulating delivery—specifically, as regulating whether manufacturers may refuse to ship 340B drugs to authorized contract pharmacies—those preemption arguments lose much of their force. Both **AstraZeneca** and the State accept, at least at this stage in the litigation, that federal law leaves largely unregulated the matter of delivery conditions. They embrace, in other words, the Third Circuit's conclusion that § 340B imposes a price term while leaving other terms essentially unspecified. *Sanofi Aventis*, 58 F.4th at 704 ("The 'purchased by' provision imposes only a price term for drug sales to covered entities, leaving all other terms blank."). One consequence of the parties' shared assumption is that a state law regulating in that area silence is less likely to conflict with any considered judgment of Congress.

At this preliminary injunction stage, the court need not conclusively resolve whether **AstraZeneca's** preferred framing of Act 143 as a price regulation is persuasive. But the court does conclude that—at least at this stage—**AstraZeneca** has not shown a likelihood, or even serious questions, that its preferred framing of Act 143 is correct. The reason, put simply, is that a state statute does not itself regulate price merely because it limits the application of its non-price regulations to the areas in which a federal price regulation applies.

***7** Begin with a hypothetical. Imagine a federal program imposing price caps on housing costs for certain veterans. But imagine that the federal program was completely silent about what kinds of background checks might properly be applied before a veteran is allowed to rent any property at the discounted price. Imagine further that, consistent with their economic incentives, some property owners sought to impose highly burdensome—and arguably unnecessary—background checks on any veterans who sought to avail themselves of the federal price cap. Those same property owners, at the same time, were perfectly willing to waive those checks for any veteran prepared to forgo the price caps and pay prevailing market rates. Now imagine that a state enacted a statute forbidding property owners from imposing burdensome background checks on veterans who sought to benefit from the federal price caps. That state statute would apply by reference to a federal pricing regulation—it would only apply when that price cap is already available because of federal law—but the state statute itself would regulate only the imposition of burdensome background checks, not price. It would not be plausible to say that the state statute itself becomes a pricing regulation merely because it uses the federal price cap to define which transactions are covered by the state rule.

At least at this early stage, **AstraZeneca** has not shown that it is any more plausible to say that Act 143 regulates pricing. The problem is that **AstraZeneca's** argument focuses on how the statute defines the drugs to which it applies rather than on the conduct the statute regulates. Act 143 defines a "340B drug" by reference to the federal pricing program, but the operative prohibition is not about price at all. Act 143 provides that no manufacturer "shall deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or shipping or delivery of a 340B drug to, a pharmacy that is under contract with a 340B covered entity and is authorized under the contract to receive and dispense 340B drugs on behalf of the covered entity." § 2(a). The regulated conduct is thus delivery and availability—whether a manufacturer may refuse to ship or deliver drugs to certain pharmacies, and to whom and when delivery must occur—not the amount charged for those drugs.

Act 143 does not impose a new price term or displace an existing one. The relevant price—the Section 340B ceiling price—continues to be established exclusively by federal law. The statute merely defines a "340B" drug as "a prescription drug that is purchased by a Section 340B covered entity through the federal Section 340B drug pricing program authorized by title 42 [U.S.C. section 256b (section 340B of the Public Health Service Act) and is dispensed by a pharmacy." Act 143 § 1. Act 143 neither sets that price nor alters the transactions to which it applies under Section 340B. Instead, the statute addresses whether manufacturers may condition delivery of replenishment drugs on the identity of the dispensing pharmacy once a covered entity has otherwise satisfied the federal eligibility criteria. That price serves as a definitional reference point does not transform the statute into a pricing regulation.

AstraZeneca rejoins that Act 143 is akin to a hypothetical statute requiring goods to be sold "for $1," Dkt. No. 21-1, at PageID.109, but that analogy is not a good fit. Act 143 does not mandate sales a price chosen by the state, nor does it cap prices at which drugs must become available to contract pharmacies. Act 143 enforces access to a price

that Congress itself imposed, in a context where the parties both assume that Congress left other terms of performance—including distribution through contract pharmacies—largely unregulated.

Nor, at this early stage in the case, does **AstraZeneca's** reliance on the replenishment model compel a different conclusion. As **AstraZeneca** emphasizes, under that model, pharmacies dispense from intermingled inventory and only later, through reconciliation, determine whether a prescription is 340B-eligible, at which point the pharmacy places a replenishment order at the discounted price. *Novartis*, 102 F.4th at 457. But that description underscores that the discounted price is already fixed by federal law. Act 143 does not dictate "what price the pharmacy and the covered entity will pay the manufacturer," *PhRMA v. Morrisey*, 760 F. Supp. 3d 439, 455 (S.D. W. Va. 2024); it governs whether manufacturers may refuse to *deliver* replenishment drugs at that federally defined price once eligibility has been established. The statute's operation depends on price only because the federal program does—not because Hawai'i is regulating price.

***8** Finally, **AstraZeneca's** reliance on *Engine Mfrs. Ass'n v. South Coast Air Quality Mgt. Dist.*, 541 U.S. 246, 251 (2004), is misplaced. There, a district in California attempted to accomplish indirectly what federal law under the Clean Air Act expressly prohibited it from doing directly. 541 U.S. at 249-50. The question was whether local fleet rules prohibiting the purchase or lease of noncompliant vehicles avoided preemption under § 209(a) of the Clean Air Act by regulating purchases rather than the manufacture or sale of vehicles. *Id*. at 248. As **AstraZeneca** acknowledges, "treating sales restrictions and purchase restrictions differently for pre-emption purposes would make no sense." *Id*. at 255. That is true, as the Supreme Court reasoned, "[t]he manufacturer's right to sell federally approved vehicles is meaningless in the absence of a purchaser's right to buy them," *id.*, because purchase and sale are two sides of the same coin. Price and delivery, by contrast, are distinct terms of performance. A restriction on delivery may make a sale more difficult or less profitable—just as the imposition of unduly restrictive background checks might make it difficult for a veteran to benefit from a rental price cap in our hypothetical above—but it operates on a different component of the transaction. This is not "meaningless semantics." *Id*. at 255. In short, price governs the economic terms of exchange; delivery governs access. Regulating one does not inherently regulate the other.

For these reasons, the court concludes that **AstraZeneca** has not shown a likelihood of success on, or serious questions going to, the merits of its threshold argument that Act 143 regulates price rather than delivery.

B. The Presumption Against Preemption Applies Here

AstraZeneca's other threshold argument is that the presumption against preemption should not apply here. The court concludes that, at this early stage, **AstraZeneca** has not shown a likelihood of success on, or serious questions going to the merits of, this argument.

Given that preemption carries "serious implications for federalism," courts are instructed to "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Nexus* ***Pharms***., 48 F.4th at 1045 (cleaned up); *see Wyeth*, 555 U.S. at 565 (explaining that the presumption applies in "all pre-emption cases," though it applies "particularly in those in which Congress has legislated in a field which the States have traditionally occupied" (cleaned up)). That is why, in express preemption cases, "when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily accept the reading that disfavors pre-emption." *Altria Group, Inc. v. Good*, 555 U.S. 70, 543 (2008). And it is why, in implied preemption cases, the "teaching" of the Supreme Court's "decisions enjoins seeking out conflicts between state and federal regulation where none clearly exists." *English v. Gen. Elec. Co.*, 496 U.S. 72, 90 (1990) (cleaned up).

AstraZeneca nonetheless argues that no presumption of preemption should apply here. It relies principally on *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), in which the Supreme Court declined to apply the presumption against preemption to a state law that sought to regulate a subject matter "inherently federal in character." *Id.* at 347. Act 143, in **AstraZeneca's** view, similarly seeks to regulate an inherently federal matter: "**AstraZeneca's** obligations towards 340B covered entities originate from Section 340B; are governed by Section 340B; and will terminate when **AstraZeneca** no longer participates in the 340B program." Dkt. No. 21-1, at PageID.106.

But the comparison to *Buckman* breaks down at closer look. The state statute at issue in *Buckman* purported to authorize private parties to sue medical device manufacturers for "ma[king] fraudulent representations to the Food and

Drug Administration (FDA)" while participating in a federal preapproval program. 531 U.S. at 343. In this way, the state statute sought to regulate the "relationship between a federal agency and the entity it regulates," a relationship that is "inherently federal in character." *Id.* at 347. Given that "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied," no presumption against preemption applied. *Id.* The point, in other words, was not that the state law regulated only within the confines of a federal program; what mattered was that the subject matter of its regulation was inherently federal.

***9** Act 143 does not, by contrast, seek to regulate the relationship between any federal agency and an entity it regulates—let alone to regulate alleged fraud within such a relationship. Instead, Act 143 regulates the manner in which drug manufacturers must arrange to provide drugs to hospitals and other covered entities. And as the State correctly notes, Act 143's stated purposes—"ensuring a patient's access to affordable medication, and protecting the financial savings that hospitals depend on to provide these critical services"—sound in traditional public-health concerns. Dkt. No. 43, at PageID.464. Regulation in this context, and with these goals, is a "complementary form of drug regulation" that falls within the historic police powers of a State. *Wyeth*, 555 U.S. at 578-79.

Indeed, **AstraZeneca** does not meaningfully dispute that Act 143 regulates a subject matter that would ordinarily fall within such historic powers. **AstraZeneca's** argument, instead, is that the presumption against preemption should not apply anyway, because Act 143 is not a "generally applicable state law[ ]" that "regulate[s] the sale and distribution of *all* drugs," rather than "just drugs sold within a federal program." Dkt. No. 21-1, at PageID.106. **AstraZeneca** contends, in other words, that because Act 143 only regulates public health within a federal program, rather than generally, it should not be accorded the presumption against preemption that ordinarily attaches to state laws that operate in this area.

That argument conflates the breadth of a state law with the subject matter it regulates. If a state regulates in an area that implicates "the historic primacy of state regulation of matters of health and safety," *Buckman*, 555 U.S. at 348, then the presumption against preemption applies, even if the state law only regulates that subject matter within the narrow confines of a federal program. *Accord Davidson v. Sprout Foods, Inc.*, 106 F.4th 842, 844, 852 (9th Cir. 2024) (applying the presumption against preemption to California law that simply "incorporates by reference all federal food labeling standards"). Just as the presumption against preemption would not have applied in *Buckman* even if the state law at issue had been drafted in broad and general terms (because the subject matter, in its application to fraud on the FDA, was inherently federal) the presumption against preemption still applies to Act 143, even though it only narrowly and specifically regulates within the confines of the Section 340B program (because the subject matter it regulates, within those confines, is one falling within the historic police powers of a state).

Nor is it surprising that Act 143 would focus specifically on participants in the Section 340B program. After all, **AstraZeneca** itself notes that it does not seek to impose its more onerous delivery conditions outside of the program. Dkt. No. 48, at PageID.565 (explaining that its restrictions on the use of unlimited contract pharmacies applies only to discounted Section 340B drugs, and that "**AstraZeneca's** drugs are available for acquisition by any covered entity, or for delivery to 'any pharmacy in Hawaii,' provided it pays commercial prices"). It is not unreasonable for a state to adopt a statute addressing a problem only in the specific context in which it has arisen.

And the record, at least at this early stage, lends support to the State's belief that manufacturers have specifically targeted covered entities' efforts to obtain discounted Section 340B drugs with restrictive delivery conditions—conditions they see no need to apply when a hospital or other customer purchases drugs at full price. As the State's brief explains, "[s]ince 2020, pharmaceutical manufacturers have increasingly imposed restrictions on the delivery of 340B drugs to contract pharmacies," and "[a]s of this writing, 38 manufacturers, including **AstraZeneca**, have implemented such restrictions and that number continues to rise year after year." Dkt. No. 43-1, at PageID.488. The State explains that manufacturers "used to email their policies directly to covered entities, but many no longer do so," requiring covered entities "to spend time and resources to manually check the internet for these updates on a regular basis, sometimes weekly." *Id.* at PageID.489. The State further avers that "[t]hese efforts divert critical personnel and funds away from patient care," and that "[t]racking and responding to each manufacturer's 340B shipment policy imposes a substantial burden," necessitating "a team including pharmacy personnel, compliance, and in-house and outside attorneys" that has spent "countless hours tracking, assessing, and responding to manufacturers' unilateral policies." *Id.*

***10** AstraZeneca itself apparently "has restricted contract pharmacy shipments since at least October 2020," and "has changed its policy several times," resulting in "breakdowns in communications and the use of additional resources." *Id*. at PageID.488–89. Under AstraZeneca's policy, covered entities "are only able to designate one contract pharmacy, and only if they lack an on-site pharmacy," and AstraZeneca "refuses to ship 340B drugs to that one contract pharmacy unless the entity submits patient-specific claims data to a third-party vendor chosen by AstraZeneca." *Id*. at PageID.489–90. The vendor's software includes what the State describes as "nonnegotiable, problematic terms and conditions," including provisions permitting the vendor to "revoke access to the software at any time" and capping liability at "$10,000." *Id*. According to the State, these restrictions have led covered entities to "avoid[ ] contractual relationships with community and specialty pharmacies because of the inability to access 340B drugs," decisions that "divert money away from patient care." *Id*. at PageID.490. The consequences are particularly acute where "not every pharmacy carries every drug," and where certain "high-cost drugs are only available through 'specialty pharmacies,' which typically ship the patients' drugs by mail." *Id*.

This factual context undermines AstraZeneca's claim that Act 143 improperly "targets" the federal program. The record evidence, at least at this early stage, supports the conclusion that it is, instead, the manufacturers who are targeting Section 340B participation—by "restrict[ing] the circumstances under which [they] offer[ ] [their] products at 340B-discounted prices," Dkt. No. 40, at PageID.418–19, and by imposing delivery and administrative conditions that limit covered entities' practical ability to access the discount they are entitled to under federal law. And so Act 143 specifically regulates health and safety in the context—Section 340B program participation—in which they have been challenged. That is no reason to deny the statute the presumption against preemption. [1]

Unpersuaded that Act 143 is a pricing regulation, or that the presumption against preemption is unavailable here, the court turns to AstraZeneca's specific preemption theories.

C. Act 134 Poses No Obstacle to the Section 340B Program

AstraZeneca's first preemption theory is that Act 143 "stands as an obstacle" to the Section 340B program because it upsets the balance Congress struck in that program and increases the costs of participation. Dkt. No. 21-2, at PageID.111. The State joins issue and argues that Act 143 is no obstacle to Section 340B at all.

As noted earlier, at this early stage in the litigation, both parties have accepted that Section 340B is largely silent on the question of what delivery conditions a manufacturer may impose on a covered entity's access to Section 340B drugs. As the parties have framed it, then, the conflict preemption question comes down to an assessment of what Congress' silence in Section 340B signifies. If Congress' silence on the matter of delivery reflects an intent to leave no room for additional regulation, then Act 143 could be understood as an obstacle to federal objectives. But if that silence instead reflects Congress' judgment that States would be free to exercise their historic police powers, then the premise of preemption collapses.

1. At the outset, it is worth noting that the parties' shared assumption about the silence of Section 340B on delivery conditions is not obviously correct. Granted, HRSA took the position, beginning in 1996, that Section 340B "is silent as to permissible drug distribution systems," and HRSA therefore sought to fill "gaps in the legislation" to "move the program forward." *Notice Regarding Section 602 of the Veterans Health Care Act of 1992*; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,549–50 (Aug. 23, 1996). Courts, too, have opined that the statute is "silent about delivery," *Sanofi Aventis*, 58 F.4th at 703, and that it "regulates neither the distribution of drugs to patients nor the role of pharmacies in this distribution." *AbbVie, Inc. v. Fitch*, 152 F.4th 635, 646 (5th Cir. 2025). The parties in this case embrace that view.

***11** But it is conceivable that Section 340B might properly be interpreted quite differently. Although the Third Circuit and D.C. Circuit held that Section 340B does not require manufacturers to allow covered entities to use unlimited contract pharmacies as a categorical or facial matter, the Ninth Circuit has not yet had occasion to consider whether those decisions are correct. Nor, of course, has the Supreme Court. And despite their forceful language about Section 340B's "silence" on delivery conditions as a facial matter, even the Third Circuit and D.C. Circuit decisions left open the door to potentially robust federal scrutiny of delivery conditions as applied—that is, in the particular circumstances of any geographic region or individual case. The D.C. Circuit, for example, while holding that "section 340B does not categorically prohibit manufacturers from imposing

conditions on the distribution of covered drugs to covered entities," nonetheless clarified that this holding did not "foreclose the possibility that other, more onerous conditions might violate the statute." *Novartis*, 102 F.4th at 464. It added that even the restrictions upheld in that case could be found to "violate section 340B as applied in particular circumstances." *Id.*

At the hearing on the motion, to be sure, **AstraZeneca** confirmed that it accepts the views of the Third Circuit and D.C. Circuit on these issues, and also agreed that extremely unreasonable or burdensome delivery restrictions would violate their obligation to make bona fide offers of discounted Section 340B drugs to covered entities. But even here, **AstraZeneca's** interpretation of federal law is that, short of an extreme imposition, federal law does not stand in their way. Under this interpretation, if the record in a particular case showed that a covered entity has 100 patients—and, therefore, a federal entitlement to obtain discounted drugs for each one of them—**AstraZeneca** could nonetheless adopt delivery restrictions that, in practice, make it impossible for that covered entity to obtain discounted drugs for a substantial number of those 100. In short, **AstraZeneca** accepts that federal law precludes it from acting in extreme ways, but its general position is that federal law generally does not constrain its discretion to impose whatever delivery conditions it wishes—even if those conditions substantially limit the ability of covered entities to obtain the discounted Section 340B drugs to which federal law entitles them.

But it might be possible to adopt—and the court in this case might ultimately adopt—a much more robust, expansive view of the federal requirements embedded within Section 340B. More precisely, it might be possible to interpret Section 340B as broadly authorizing a federal law challenge to any delivery condition that unreasonably limits the ability of a covered entity to take advance of manufacturers' obligation to "offer" Section 340B drugs "for purchase" at or below statutory price caps. Under this interpretation of Section 340B, any restriction of covered entities' ability to use contract pharmacies in Hawai'i could conceivably be found unlawful—either facially or at least as applied under local and current circumstances—under Section 340B itself. The result that the State seeks to accomplish under Act 143 could, on this view, instead be mandated by federal law. And it is possible to interpret the Third Circuit and D.C. Circuit decisions as being entirely compatible with this interpretation of federal law.

At least up to this point in these proceedings, however, neither party has sought to portray federal law as playing a robust role of that sort. The State does not do so; the very reason the Hawai'i Legislature adopted Act 143 was because it understood federal law as being essentially silent in this area. And **AstraZeneca**, at least to this stage in the litigation, has not meaningfully disavowed the position it took in the D.C. Circuit: that federal law gives it "a nearly unfettered ability to impose conditions." *Id.* at 459. Although the court ultimately need not accept the parties' shared assumption about the proper interpretation of federal law, it is appropriate at this stage—in which the court is only assessing whether **AstraZeneca** has shown a likelihood of success on the merits to warrant the extraordinary relief of a preliminary injunction—to focus squarely on whether the moving party's own arguments, including its assumptions about the breadth of federal law, make that showing.

***12** 2. The parties' shared assumption that Section 340B is largely silent on the question of delivery conditions stacks the deck in the State's favor at this early stage in the case. That is because the less involved federal law is in regulating proper delivery conditions, the less likely it is that Congress meant for federal law to have an exclusive say. And so while **AstraZeneca** repeatedly asserts that Congress "carefully balanced" the burdens and benefits of participation in the 340B program and that Act 143 disrupts that calibration by increasing manufacturers' costs, Dkt. No. 121-1, at PageID.111, **AstraZeneca's** assertion is weakened by its assumption that federal law is largely silent on the matters that Act 143 aims to regulate.

Put differently, it is difficult to conclude that if Section 340B leaves delivery conditions almost entirely unregulated, that this was because Congress made the deliberate determination to leave it to manufacturers—who have a financial interest in making it as difficult as possible for covered entities to obtain discounted Section 340B drugs—to decide how difficult it should be. The purpose of Section 340B is not to make it as difficult as manufacturers would like it to be for covered entities to obtain discounted drugs. Rather, the "purpose of Section 340B is clear—it provides discounts on drugs to certain kinds of healthcare facilities. To that end, the more opportunities that covered entities have to purchase discounted drugs, the more money they can save." *Novartis* ***Pharms****. Corp. v. Espinosa*, No. 21-CV-1479 (DLF), 2021 WL 5161783, at *7 (D.D.C. Nov. 5, 2021). And Section 340B entitles covered entities to discounted prices for Section 340B drugs for each of their eligible patients; the

statute contains no limit on the number of discounted drugs covered entities may obtain. The court cannot discern, in the assumed silence of the federal statute, any congressional intent to undermine the right of covered entities to obtain these discounted drugs through the roundabout mechanism of allowing manufacturers to impose, at will, whatever onerous delivery conditions they like.

AstraZeneca nonetheless contends that the silence should be construed as reflecting Congress' considered decision to entrust manufacturers with this unfettered authority. The court is not convinced. It is true that, as the D.C. Circuit observed, "[s]tatutory silence implies that manufacturers may impose distribution conditions by contract, not that they are prohibited from doing so." *Novartis*, 102 F.4th at 460. But the D.C. Circuit's observation concerned the scope of federal law. It does not answer the preemption question of whether federal law is meant to be exclusive. And in considering preemption, the court must be mindful that "[o]rdinarily, state causes of action are not pre-empted solely because they impose liability over and above that authorized by federal law." *English*, 496 U.S. at 89.

In *English*, for example, the Supreme Court concluded that even though federal law preempted the field of "radiological safety aspects involved in the construction and operation of a nuclear plant," a nuclear plant employee's state law tort claims for workplace misconduct were not preempted. *Id.* at 82. The Court reached that conclusion even though federal law provided a remedial scheme for addressing similar complaints and required that they be filed within 30 days of an alleged violation. *Id.* at 76-78. Although the state law claim was not similarly time-constrained, the Court rejected the argument that it should be preempted to ensure that nuclear plant employees did not have "less incentive" to use the federal remedial scheme. *Id.* at 89. Perhaps the robust state regime would make the federal scheme less attractive, the Court acknowledged, but "[s]uch a prospect is simply too speculative a basis on which to rest a finding of pre-emption." *Id.* at 90.

***13** Or consider *Chamber of Commerce of U.S. v. Whiting*, 563 U.S. 582 (2011). There, the Supreme Court rejected an obstacle preemption challenge to an Arizona state statute requiring employers to verify the employment eligibility of its employees using the federal "E-Verify" program. *Id.* at 607-10. Although Congress had passed the legislation "setting up the program that includes E-Verify," it chose to "constrain federal action: Absent a prior violation of federal law, 'the Secretary of Homeland Security may not require any person or other entity [outside of the Federal Government] to participate in a pilot program' such as E-Verify." *Id.* at 608. The Court rejected the argument that this prohibition on federal action should preempt a state effort to require more. *Id.* at 609-10.

The Ninth Circuit reached a similar conclusion in *City of Los Angeles v. AECOM Servs, Inc.*, 854 F.3d 1149 (9th Cir. 2017). The question in that case was whether a state-law claim for *de facto* contribution—based on the allegation that a contractor failed to comply with federal law—was preempted by Title II of the Americans with Disabilities Act or Section 504 of the Rehabilitation Act of 1974, neither of which authorized a contribution claim. Rejecting the argument that Congress' silence should be construed as a judgment that state law should be preempted, the Ninth Circuit explained that treating "congressional *omission*" as a basis for preempting state law would "turn[ ] the presumption against preemption on its head." *Id.* at 1160. "The basic premise of the presumption is that absent an affirmative indication to the contrary, a federal regulation will not preempt state law." *Id.*; *accord Davidson v. Sprout Foods, Inc.*, 106 F.4th at 850 (rejecting the argument that a federal statute's "prohibition of private enforcement" should be construed "as evidence of Congress' intent to preempt private enforcement of [a] state law" that incorporated federal law standards, and noting that the argument would "read too much" into the federal statute's omission, "which relates only to the enforcement of federal law" and "does not limit enforcement of state law").

The bottom line is that "congressional and regulatory silence usually defeats a claim of preemption, not the other way around." *Planned Parenthood of Indiana, Inc. v. Commissioner of Indiana State Department of Health*, 699 F.3d 962, 985 (7th Cir. 2012). Accepting—at this early stage in the case—**AstraZeneca's** assumption that Section 340B is largely silent on delivery conditions, the court concludes **AstraZeneca** has not shown a likelihood of success on the merits of its conflict preemption claim based on Section 340B.

3. Resisting this conclusion, **AstraZeneca** urges the court to conclude that Act 143 undermines the national uniformity of the Section 340B program, particularly as other states enact similar but not identical statutes. Dkt. No. 21-1, at PageID.115. On this point, **AstraZeneca** raises a legitimate concern. Congress undoubtedly sought nationwide uniformity in the administration of the Section 340B pricing obligation, and the Supreme Court has emphasized

the importance of centralized federal enforcement in that context. *Astra*, 563 U.S. 110, 121. The Section 340B statute establishes a detailed federal enforcement regime, administered by HHS and supported by audits, refunds, civil monetary penalties, and administrative dispute resolution. 42 U.S.C. §§ 256b(a)(5), (d)(1), (d)(3).

But Act 143 does not authorize private parties to enforce Section 340B pricing obligations, nor does it purport to administer the federal program. Manufacturers' obligations under Section 340B remain defined by federal law, as interpreted by federal courts, and enforced by federal officials. Act 143 instead creates state law obligations governing the delivery of drugs through pharmacies operating under state law—a subject on which the parties jointly assume Congress is largely silent. In that respect, Act 143 operates alongside, rather than in place of, the federal enforcement regime.

14** **AstraZeneca** nevertheless relies on *Buckman*, 531 U.S. 341, to argue that Act 143 establishes a parallel enforcement scheme that impermissibly intrudes upon federal prerogatives. That analogy is unpersuasive. The concern in *Buckman* was that state-law "fraud-on-the-FDA" claims would undermine the FDA's "delicate balance of statutory objectives" in deciding how aggressively to exercise its own enforcement authority. *Id.* at 348–49; *accord* *Nexus **Pharms., 48 F.4th at 1048 (concluding that a state statute was preempted because it would interfere with "FDA's enforcement discretion by enabling what the FDA regards as over-enforcement").

In this case, by contrast, the parties jointly accept that federal law is largely silent on the question of delivery restrictions. A silent federal statute does not call on a federal agency to exercise any delicate balance of statutory objectives, or to make nuanced judgment calls about how aggressively to enforce the law. It allows little or no role for the federal agency at all. Nor is that silence fairly understood as reflecting Congress' own careful balancing of statutory objectives. Given the way the parties have jointly chosen to characterize the role of federal law at this early stage in the litigation, the court does not find that state law requirements would conflict with any federal exercise of enforcement or policy discretion.

For similar reasons, the court concludes, at this stage, that **AstraZeneca** has not shown a sufficient likelihood of success on (or serious questions about) the merits of its contention that Act 143 targets some uniquely federal interest embedded within Spending Clause legislation. Dkt. No. 76, at PageID.745-46 (quoting *Boyle v. United Techs. Corp.*, 487 U.S. 500, 504, 507 (1988)). The parties' agreement that federal law is largely silent on the matter of delivery restrictions suggests, instead, that Congress has not expressed any meaningful interest on that matter.

Nor does Act 143 present a substantial risk of conflicting adjudications sufficient to support obstacle preemption. **AstraZeneca** suggests that, in a state enforcement proceeding, a manufacturer might assert as a defense that the drugs at issue were not required to be sold at the 340B price under federal law, potentially forcing state courts to resolve federal questions. Dkt. No. 21-1, at PageID.115. It is also conceivable that, as the evidentiary record develops in this case, **AstraZeneca** is ultimately able to show that such a significant amount of unlawful diversion is occurring in Hawai'i that it is appropriate to view Act 143, as applied, as effectively requiring pricing discounts in situations in which federal law does not authorize them. But such conflicts are, at this stage, "too speculative a basis on which to rest a finding of pre-emption." *English*, 496 U.S. at 90. While **AstraZeneca** has conducted limited expedited discovery on the replenishment model and how it is used in Hawai'i, it has not, at least this stage, offered any evidence that any covered entity in Hawai'i is engaged in unlawful diversion. And at this stage, the prospect of conflicting adjudication about what might count as diversion is likewise mere speculation. As the Supreme Court has cautioned, preemption is "ordinarily not to be implied absent an 'actual conflict.' " *Id.* Accepting, for now, the parties' assumption that Section 340B does not meaningfully regulate delivery conditions and does not empower HRSA to do so, state enforcement of state-law delivery requirements does not create the kind of parallel enforcement regime condemned in *Astra* or *Buckman*.

***15** In short, while Congress sought national uniformity with respect to the pricing obligations imposed by Section 340B, no party has sought to develop the argument Congress sought any such uniformity for matters of delivery and distribution. Act 143 operates in that space in which Congress is said to have been silent. Under these circumstances, the speculative possibility of overlapping adjudication or enforcement is not enough for **AstraZeneca** to show a likelihood of success on, or serious questions going to, the merits of its obstacle preemption claim.

4. At the hearing on the motion, **AstraZeneca** more fully developed an alternative argument: that Act 143 is preempted

because it amounts to an impermissible direct regulation of federal contractors, those contractors being the drug manufacturers who enter into contracts with the government to participate in Medicare and Medicaid. This argument does not fall neatly into the doctrinal boundaries of conflict preemption based on the Section 340B program. It is instead invokes a separate preemption doctrine concerned with intergovernmental immunity.

At least at this stage, **AstraZeneca** has not shown a likelihood of success on—or even serious questions going to—the merits of this argument. The intergovernmental immunity doctrine has its roots in *McCulloch v. Maryland*, 17 U.S. 316 (1819), in which the Supreme Court held unconstitutional Maryland's attempt to impose a tax on the Bank of the United States. As Chief Justice John Marshall explained, under the Supremacy Clause, "the States have no power, by taxation or otherwise, to retard, impede, burden, or in any manner control, the operations of the constitutional laws enacted by Congress to carry into execution the powers vested in the general government." *Id.* at 436. The doctrine eventually expanded to bar "any state law whose 'effect ... was or might be to increase the cost to the Federal Government of performing its functions,' including laws that imposed costs on federal contractors." *United States v. Washington*, 596 U.S. 832, 838 (2022) (quoting *United States v. County of Fresno*, 429 U.S. 452, 460 (1977)). So long as the federal government was picking up the tab, the states had no power to make the charge. *See County of Fresno*, 429 U.S. at 460 (explaining that "[f]or many years the Court read the decision in *McCulloch* as forbidding taxes on those who had contractual relationships with the Federal Government or with its instrumentalities whenever the effect of the tax was or might be to increase the cost to the Federal Government of performing its functions").

The Supreme Court more recently has narrowed the intergovernmental immunity doctrine. Under the current formulation, a state law that seeks to directly regulate the operations of the United States is still preempted. But when the state law imposes a financial cost on the federal government, that is no longer a showstopper. Courts must instead ask a further question: does the state law discriminate against the federal government, or is it instead generally applicable or neutrally applied? Under this branch of the intergovernmental immunity doctrine, "a state law is thus no longer unconstitutional just because it indirectly increases costs for the Federal Government, so long as the law imposes those costs in a neutral, nondiscriminatory way." *Washington*, 596 U.S. at 839.

Turn back now to Act 143. Does it directly regulate the operations of the United States? There is no persuasive argument that it does. Act 143 prohibits drug manufacturers from imposing certain delivery conditions on the distribution of Section 340B drugs to covered entities. Those state law requirements do not in any way apply to the United States or any of its agencies or employees. And while it may be appropriate to characterize drug manufacturers that participate in the Section 340B program as federal contractors, that generalized status is not the relevant question. A state enforcement action compelling such a drug manufacturer to stop acting in a certain way within a state's boundaries would directly regulate the manufacturer. But if the manufacturer was not acting at the direction or instruction of the federal government, then the manufacturer is being regulated for its own conduct, not for conduct it has undertaken as an instrumentality of the United States. Here, the federal government has not ordered or instructed manufacturers to impose restrictions on the ability of covered entities to obtain Section 340B drugs using outside pharmacies; hence, when states regulate manufacturers' efforts to do what federal law does not instruct them to do, the state laws are not regulating any act compelled or directed by the federal government, but instead the private conduct (and choices) of the manufacturers themselves.

***16** Nor has **AstraZeneca** shown, at this stage in the case, that there is any sense in which the federal government could be said to bear the costs of Act 143. While it is possible that further discovery or presentation of evidence could alter this picture, the current record shows only that manufacturers themselves bear the (potentially considerable) cost. This matters because if the federal government is not bearing the burden of a state law, then there is no occasion to the turn to the follow-on question of whether the state law imposing that burden on the federal government is generally applicable.

Take the Supreme Court's decision in *Washington*, for example—on which, at the hearing, **AstraZeneca** itself placed heavy reliance. There, the state sought to apply a worker's compensation regime "only to a 'person, including a contractor or subcontractor, who was engaged in the performance of work, either directly or indirectly, for the United States.' " 596 U.S. at 839. This law "impos[ed] on the Federal Government costs that state or private entities do not bear," *id.*, and it did this because "the Federal Government pa[id] workers' compensation claims for federal contractors,"

id. at 836. *See also id.* (explaining that because the federal government covered the costs to federal contractors, the state law "increase[d] workers' compensation costs for the Federal Government"). It was only because of that financial burden on the federal government that the Supreme Court turned to the question of whether the burden flowed from a generally applicable state law (which, in that case, the Court readily concluded it did not).

And so while **AstraZeneca** makes a persuasive argument that Act 143 is not generally applicable, that argument does not aid **AstraZeneca** in showing a likelihood of success on the merits, precisely because the question of general applicability is not implicated if the federal government does not bear the financial burden of the state law in the first place. As noted, **AstraZeneca** has not—at least to this point in the case—shown that the federal government bears, either directly or indirectly, any amount of the costs of Act 143 on the manufacturers. To the contrary, the evidence at this stage suggests that **AstraZeneca** is bearing these costs entirely itself—which is, in fact, precisely the reason it argues that it faces irreparable injury from Act 143.

For these reasons—and recognizing that, at least at this stage, **AstraZeneca** has not yet had occasion to thoroughly brief the argument of intergovernmental immunity, and may well be able to present stronger evidence at a later stage—the court concludes that **AstraZeneca** has not shown a likelihood of success on, or even serious questions going to, the merits of this argument.

D. Whether Act 143 is Preempted by Federal Patent Law

AstraZeneca's second theory in favor of a preliminary injunction is that Act 143 is preempted by federal patent law. But this theory rests on a premise the Supreme Court has never endorsed: that federal patent law shields all patent-holders from downstream economic regulation that incidentally affects profits. **AstraZeneca** asserts that States may not "upset [the] finely calibrated system" of patent incentives by regulating prices and insists that Act 143 impermissibly constrains a manufacturer's "opportunity" to enjoy the benefits of exclusivity. *Id.*, at PageID.117–18. But the cases **AstraZeneca** cites protect the right to exclude competitors, not a right to maximize revenue in every regulated market.

As the Supreme Court has explained, federal patent law prevents states from granting patent-like exclusivity or authorizing copying of protected inventions. *Bonito Boats*, 489 U.S. at 152 ("[S]tate regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws."). **AstraZeneca** has not, at this stage, shown a likelihood of success in (or serious questions going to the merits of) its argument that Act 143 authorizes copying, compulsory licensing, or any of the other activities generally prohibited under federal patent law. Under Act 143 and other state regulations like it, **AstraZeneca** retains "the full exercise of the exclusionary power that derives from a patent," *id.*, because no competitor is permitted to manufacture or sell its patented drugs. Act 143 regulates only the terms of certain commercial transactions in a heavily regulated pharmaceutical marketplace. A state law does not run up against patent preemption simply because it affects the price at which a patent-holder chooses to participate in that marketplace.

***17** **AstraZeneca** relies on *Biotechnology Indus. Org. v. D.C.* ("*BIO*"), arguing that Act 143 "re-balance[s] the statutory framework of rewards and incentives" by "diminishing the reward to patentees." Dkt. No. 21-1 at PageID.118–19 (quoting *BIO*, 496 F.3d 1362, 1374 (Fed. Cir. 2007)). But *BIO* involved a statute that directly altered the competitive structure Congress created in the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the "Hatch–Waxman Act") by policing the "proper balance between innovators' profit and consumer access." 496 F.3d at 1374. The text of Act 143 does not change who may compete with **AstraZeneca**, when competition may occur, or the duration of **AstraZeneca's** patents' exclusivity. It leaves the patent bargain intact: **AstraZeneca** alone may make and sell its patented products. The Act affects a subset of sales, and not the existence or scope of the patent as an "exclusive" right. *Id.* at 1372. And any emphasis on reduced "financial savings" and diminished "reward[s]" does not establish conflict preemption. Dkt. No. 21-1 at PageID.119. Looking again to *BIO*, the court there held that the challenged statute was preempted because its "operation st[ood] largely—indeed, exclusively—within the scope of the patent laws," and because it penalized high prices in a manner that "shift[ed] the benefits of a patented invention from inventors to consumers" by "limiting the full exercise of the exclusionary power that derives from a patent." 496 F.3d at 1373-74. Act 143 does none of that. It neither caps the price of patented drugs nor penalizes high prices as such, and it applies regardless of whether the drugs are subject to patent.

More fundamentally, federal patent law's purpose is to balance innovation and competition; it does not guarantee patentees a particular return. *See Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230–31 (1964) ("[T]he patent system is one in which uniform federal standards are carefully used to promote invention while at the same time preserving free competition."). Patent law protects the right to exclude others from making or selling the invention; it does not police profit margins or insulate patentees from downstream financial effects of regulation. *Kimble v. Marvel Ent., LLC*, 576 U.S. 446, 451 (2015) ("Patents endow their holders with certain superpowers, but only for a limited time."). To be sure, changes in market conditions may affect a patent holder's investment-backed expectations. But if any law that reduced a patent-holder's margins were preempted, vast areas of traditional state regulation would be suspect.

Moreover, here, the record developed to date does not show that **AstraZeneca** is prevented from inventing or manufacturing its patented drugs. And the record does not demonstrate that contract pharmacy sales, in particular, have altered **AstraZeneca's** incentives to invest in or supply its patented products. Rather, **AstraZeneca's** allegations concern the ability of covered entities and contract pharmacies to capture economic advantages associated with distribution through the 340B program. *See* Dkt. No. 40, at PageID.406-07 ("[T]he boom in contract pharmacy sales has been fueled by the prospect of outsized profit margins on 340B-discounted drugs."). But those dynamics reflect issues of unanticipated demand, not interference with the patent right itself. *See, e.g.*, *Pfizer, Inc. v. Heckler*, 735 F.2d 1502, 1513 (D.C. Cir. 1984) ("While the patent holder may exercise control over the supply of the product to the market and the number of suppliers, its lawful power to exclude others does not include the power to prevent consumers from responding prudently to any competitive market conditions created by the patent holder.").

Finally, **AstraZeneca's** fallback argument—that Act 143 is preempted even if characterized as a distribution regulation because it imposes a "costly obligation" that diminishes patent rewards—is unpersuasive. *See* Dkt. No. 21-1, at PageID.118-19. Under that theory, any regulation increasing the cost of selling or distributing patented goods would be per se invalid. But ordinary economic burdens do not equal interference with the patent right itself. And **AstraZeneca** identifies only an economic effect, not an intrusion into the core of its patents.[2] That is insufficient to establish patent preemption.

***18** In short, for **AstraZeneca** to succeed on the merits of a patent preemption claim, it would have to show that state law obstructs Congress' objectives in establishing the patent system. *See, e.g.*, *Sears, Roebuck & Co.*, 376 U.S. at 231 ("Obviously a State could not, consistently with the Supremacy Clause of the Constitution, extend the life of a patent beyond its expiration date or give a patent on an article which lacked the level of invention required for federal patents."). **AstraZeneca** is unlikely to persuade the court that Act 143 "re-balance[s] the statutory framework of rewards and incentives" established by Congress, and indeed has not shown any serious questions going to the merits of that argument. *BIO*, 496 F.3d 1362, 1374. It therefore does not meet the standard for a preliminary injunction on that basis.

CONCLUSION

A preliminary injunction is an extraordinary form of relief, which a court may not lightly grant. On the present record, **AstraZeneca** has not carried its burden to establish a likelihood of success on, or serious questions going to the merits of, its federal preemption claims. Its motion for a preliminary injunction is therefore DENIED.

IT IS SO ORDERED.

All Citations

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Footnotes

1 To be clear, the court does not adopt, at least at this early stage in the litigation, the State's suggestion that **AstraZeneca** and other manufacturers are adopting these 340B-specific restrictions in a bad faith effort to undermine the access of covered entities to discounted drugs. **AstraZeneca** contends that it has adopted

some restrictions on the use of outside pharmacies, for example, because of concerns with impermissible diversion. The point here is simply that in the face of manufacturers' restrictions targeting the Section 340B program (whatever the motivation), it is not unreasonable for the State to adopt a statute that specifically addresses these restrictions in the context in which they have arisen.

2 The district court decisions **AstraZeneca** invokes do not establish that it has succeeded on the merits of its patent preemption claims. **AstraZeneca** relies on an order concluding that, "taking **AstraZeneca's** allegations as true," the complaint plausibly established a "right to relief." Dkt. No. 48, at PageID.570-71 (citing ***AstraZeneca Pharms. LP*** *v. McClain*, No. 4:24-cv-268-KGB, 2025 WL 4092197, at *7 (E.D. Ark. Sept. 30, 2025). But the court in that case considered a motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c). A ruling that allegations must be accepted as true for those purposes does not establish that Act 143 in fact conflicts with federal patent law such that it is likely to succeed on the merits of those claims.

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