McCORRISTON MILLER MUKAI MacKINNON LLP

DAVID J. MINKIN 3639-0
BRETT R. TOBIN 9490-0
Five Waterfront Plaza, 4th Floor
500 Ala Moana Boulevard
Honolulu, Hawai‘i 96813
Telephone: (808) 529-7300
Facsimile: (808) 524-8293
E-mail: djminkin@m4law.com;
tobin@m4law.com

Attorneys for Plaintiff
ASTRAZENECA PHARMACEUTICALS LP

IN THE UNITED STATES DISTRICT COURT

DISTRICT OF HAWAI‘I

ASTRAZENECA PHARMACEUTICALS LP, Plaintiff, vs. ANNE E. LOPEZ, in her official capacity as the ATTORNEY GENERAL OF THE STATE OF HAWAII, Defendant.	CIVIL NO. PLAINTIFF ASTRAZENECA PHARMACEUTICALS LP'S COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF; SUMMONS

PLAINTIFF ASTRAZENECA PHARMACEUTICALS LP'S COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Section 340B of the federal Public Health Service Act, 42 U.S.C. § 256b, requires pharmaceutical manufacturers to "offer" their products at steeply discounted rates to an enumerated and clearly defined list of "covered entities." Such price controls can disincentivize innovation and destabilize markets, and Congress carefully crafted Section 340B and limited participation in the program to fifteen—and only fifteen—types of covered entities. Off-site, for-profit pharmacy chains (like CVS or Walgreens) were *not* included on the list of covered entities.

2. In fact, federal courts have already rebuffed efforts to force manufacturers to offer 340B-discounted drugs for sales occurring through these so-called "contract pharmacies." The U.S. Court of Appeals for the Third Circuit held that Plaintiff AstraZeneca Pharmaceuticals LP's ("***AstraZeneca***" or "***Plaintiff***") decision to restrict the offer of 340B-discounted drugs for contract pharmacy sales "do[es] not violate Section 340B," and it "enjoin[ed] [federal officials] from enforcing against" AstraZeneca any "reading of Section 340B" that would require AstraZeneca to make 340B discounts available for sales at "an unlimited number of contract pharmacies." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 706 (3d Cir. 2023). The Third Circuit's decision was then incorporated into a permanent

injunction, issued by the federal district court in Delaware, protecting AstraZeneca's right to proceed with its contract pharmacy policy.

3. The D.C. Circuit has joined the Third Circuit, similarly "reject[ing] [the] position that section 340B prohibits drug manufacturers from imposing any conditions on" the offer of "discounted drugs to covered entities" who use contract pharmacies. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 459 (D.C. Cir. 2024).

4. The State of Hawaii took the opposite side of that dispute. It filed amicus briefs in the Third and D.C. Circuits arguing that "[m]anufacturers should not be allowed to unilaterally restrict covered entities' use of contract pharmacies and thereby eliminate the significant revenue" that it generates. *See* Br. of Amici Curiae States, *Sanofi Aventis*, 2022 WL 1617655, at *9; *see also* Br. of Amici Curiae States, *Novartis Pharms.*, 2022 WL 1644996, at *2 (arguing manufacturers who "limit[] 340B covered entities to using a single retail community pharmacy" are thereby "flout[ing] their statutory obligation to offer safety-net providers 340B-discounted prices on critical prescription drugs.").

5. Dissatisfied with the scope of federal law, on May 30, 2025, Hawaii enacted a statute seeking to give the 340B program precisely the same scope as a matter of *state* law that federal courts have rejected as a matter of *federal* law. Known as Act 143, the Hawaii statute requires pharmaceutical manufacturers to

offer 340B-discounted pricing for sales at an unlimited number of contract pharmacies.

6. Act 143 prohibits manufacturers from "deny[ing], restrict[ing], or prohibit[ing], 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 340B covered entity." Act 143 § 2-2(a).

7. The law thus extends Section 340B's price caps beyond the scope of the federal program to reach unlimited contract pharmacy sales—in effect, vastly expanding discounts under the federal 340B program to an entirely new category of transactions. This expansion under state law directly conflicts with federal law.

8. AstraZeneca brings this action to enjoin enforcement of Act 143. AstraZeneca argues that the Act cannot validly be enforced against AstraZeneca for four separate and independent reasons.

9. ***First***, Act 143 creates a conflict with—and thus is preempted by—federal law under the Supremacy Clause of the U.S. Constitution. *See* U.S. Const. art. VI, cl. 2. Rulings of the Third and D.C. Circuits make clear that the federal 340B statute does *not* obligate manufacturers to deliver discounted drugs to unlimited contract pharmacies. State officials may not impose this obligation on AstraZeneca either. Nor may any State engraft new, costly obligations under state

law onto an existing federal benefits program—especially not one, like the 340B program, that involves nationally uniform standards and exclusive enforcement by federal agencies.

10. ***Second***, Act 143 creates a conflict with—and thus is preempted by—federal patent law. In *Biotechnology Industry Organization* (*BIO*) *v. District of Columbia*, the Federal Circuit squarely held that federal patent law "prohibits states from regulating the price of patented goods." 496 F.3d 1362, 1372 (Fed. Cir. 2007). Yet Act 143 does precisely that. It requires manufacturers like AstraZeneca to offer steeply discounted prices for the sale of their patented drugs, thereby extending federal price caps to an additional category of patented drug sales (contract pharmacy sales) that federal courts have held are *not* required under the 340B program.

11. ***Third***, Act 143 violates the Contracts Clause of the U.S. Constitution. *See* U.S. Const. art. I, § 10, cl. 1. The 340B program is enforced through agreements between drug manufacturers and the Secretary of the U.S. Department of Health and Human Services (HHS). 42 U.S.C. § 256b(a)(1). Act 143 substantially interferes with the operation of those agreements, and with manufacturers' rights and obligations thereunder, by imposing costly new obligations only on manufacturers who sign such agreements.

12. ***Fourth***, Act 143 violates the U.S. Constitution's Takings Clause. *See* U.S. Const. amend. V. Under the Takings Clause, "the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*," a prohibition that applies regardless of whether "*A* is paid just compensation." *Kelo v. City of New London*, 545 U.S. 469, 477 (2005). But Act 143 requires manufacturers like AstraZeneca to transfer their property (prescription drugs) to other private parties (covered entities and the pharmacies with which they contract). This forced transfer would be unlawful even if manufacturers were paid just compensation for these contract pharmacy sales. But in fact, they are not: Manufacturers are compensated at steeply discounted prices, well below fair market value.

13. AstraZeneca therefore seeks an order: (1) declaring that Act 143 is preempted by Section 340B; (2) declaring that Act 143 is preempted by federal patent law as applied to AstraZeneca's patented products; (3) declaring that Act 143 is unconstitutional as applied to AstraZeneca under the federal Contracts Clause; (4) declaring that Act 143 is unconstitutional as applied to AstraZeneca under the federal Takings Clause; and (5) enjoining Defendant Hawaii Attorney General Anne Lopez and any other Hawaii officials from enforcing Act 143 against AstraZeneca through investigative demands, administrative proceedings, lawsuits seeking civil penalties or other relief, or in any other manner.

JURISDICTION AND VENUE

14. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (action arising under the Constitution of the United States) and 28 U.S.C. § 1338(a) (civil action arising under any Act of Congress relating to patents). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other relief pursuant to 28 U.S.C. §§ 2201-02.

15. This Court also has inherent equitable powers to enjoin actions of state officials that contradict the federal Constitution or federal law. *See Ex parte Young*, 209 U.S. 123, 159-60 (1908); *accord, e.g.*, *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949).

16. Venue is proper in this Court under 28 U.S.C. § 1391(b)(2) because this action challenges a Hawaii law that applies to and purports to regulate the sale of AstraZeneca's products in this District. AstraZeneca makes its drugs available and offers its products to multiple 340B-covered entities within this District, and these entities maintain multiple contract pharmacy arrangements. The challenged law (if not invalidated) would apply to conduct and property in this District, including AstraZeneca's, and is highly likely to be enforced in this District.

17. Venue is also proper in this Court under 28 U.S.C. § 1391(b)(1) because Defendant maintains offices in this District, through which Defendant would enforce the law challenged in this action.

PARTIES TO THE ACTION

18. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware with its principal place of business in Wilmington, Delaware. AstraZeneca is a biopharmaceutical company focusing on the discovery, development, manufacturing, and commercialization of medicines. AstraZeneca participates in the 340B program.

19. Defendant Anne E. Lopez is the Attorney General of Hawaii. In that capacity, she enforces the challenged legislation. This suit is brought against her in her official capacity only. The Attorney General maintains an office in Honolulu, Hawaii.

FACTUAL ALLEGATIONS

The Federal 340B Program Caps Drug Prices for Enumerated Covered Entities that Provide Healthcare to Certain Underserved Populations

20. Section 340B of the Public Health Service Act established a federal program that "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities," known as covered entities, that provide healthcare to certain underserved populations. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011).

21. As a condition of receiving coverage and reimbursement for its drugs under Medicaid and Medicare Part B, a pharmaceutical manufacturer must enter into a pharmaceutical pricing agreement with HHS. *See* 42 U.S.C. § 256b(a)(1). In that agreement, the manufacturer must "offer each covered entity covered outpatient drugs for purchase" at a specified discount price "if such drug is made available to any other purchaser at any price." *Id.* This is known as Section 340B's "must-offer" requirement. Manufacturers that "knowingly and intentionally charge[] a covered entity a price for purchase of a drug that exceeds the [340B discount price]" are subject to civil monetary penalties. *Id.* § 256b(d)(1)(B)(vi)(III).

22. The 340B statute also regulates covered entities, which may not obtain 340B pricing on units of drugs for which a manufacturer pays a Medicaid rebate (known as "duplicate discounts"), nor resell or otherwise transfer such drugs to persons other than their patients (known as "diversion"). *Id.* § 256b(a)(5)(A), (B).

23. Congress enacted Section 340B to give covered entities access to prescription drugs at below-market prices, thereby helping them serve their uninsured and indigent patients. H.R. Rep. No. 102-384, pt. 2, at 7 (1992). Balanced against its goal of increasing access, however, Congress also recognized the need to "assure the integrity of the drug price limitation program." *Id.* at 16.

24. Congress has added to the list of 340B-covered entities over time, and today there are fifteen delineated categories of covered entities. 42 U.S.C. § 256b(a)(4)(A)-(O).

25. Notably, Congress has *never* included contract pharmacies in the statutorily defined list of facilities that qualify as covered entities. Indeed, in drafting what would become the 340B statute, Congress considered proposed language that would have permitted covered entities to dispense 340B drugs through *on-site* contractors providing pharmacy services. *See* S. Rep. No. 102-259, at 1-2 (1992) (requiring manufacturers to provide a discounted price for drugs that are "purchased and dispensed by, or under a contract entered into for *on-site pharmacy services* with" certain enumerated covered entities) (emphasis added). But that provision was not enacted.

26. The 340B program has its own federal enforcement provisions and administrative dispute-resolution process. Congress required the Secretary of HHS to establish an adjudicatory body to resolve disputes among participants in the 340B program, including "claims by covered entities that they have been overcharged for drugs purchased under this section [340B], and claims by manufacturers … of violations" by covered entities. 42 U.S.C. § 256b(d)(3)(A). Under that statutory mandate, the Health Resources and Services Administration ("***HRSA***"), the subagency of HHS that oversees the 340B program, has established

"requirements and procedures for the 340B Program's administrative dispute resolution (ADR) process." 85 Fed. Reg. at 80,632 (Dec. 14, 2020). The ADR Rule authorizes panels of federal officers to resolve claims for "monetary damages," as well as other unspecified "equitable relief" sought by claimants. 42 C.F.R. § 10.21(a). And it empowers ADR panels to address a range of factual and legal disputes, including "those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales." 85 Fed. Reg. at 80,636.

27. Importantly, before a manufacturer may access the ADR process, HRSA requires the manufacturer to first audit a covered entity. *See* 42 U.S.C. § 256b(d)(3)(B)(iv); 89 Fed. Reg. 28,643, 28,645 (Apr. 19, 2024) ("[M]anufacturers are required to audit a covered entity prior to filing an ADR claim"). And under HRSA regulations, a manufacturer may only initiate an audit when it can point to "documentation which indicates that there is reasonable cause," with "reasonable cause" defined to mean "that a reasonable person could believe that a covered entity may have violated" the prohibitions on diversion or duplicate discounting. 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). Thus, absent such "documentation," the ADR process is unavailable to a manufacturer.

28. HRSA revised the ADR Rule last year. *See* 89 Fed. Reg. at 28,643. Among other things, the revised rule gives "340B ADR Panel[s]" responsibility to resolve disputes related to "overcharge[s]," which include claims that a

manufacturer has "limited [a] covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling prices." 42 C.F.R. §§ 10.3, 10.21.

Contract Pharmacy Use Leads to Abuse and Profiteering

29. Section 340B does not require manufacturers to offer 340B-discounted drugs to contract pharmacies—or indeed, to *any* entity not specifically enumerated in the statute. In the decades since the enactment of the program, however, HRSA has issued two non-binding "guidance" documents purporting to authorize covered entities to enter into agreements with contract pharmacies to dispense outpatient drugs under Section 340B.

30. In 1996, HRSA issued guidance providing that "eligible covered entities that do not have access to appropriate 'in-house' pharmacy services" could now enter into an agreement with a *single* outside pharmacy of its choice to provide such services for 340B drugs. 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996) (1996 Guidance).

31. Then, in 2010, HRSA released new guidance stating that covered entities could now "use multiple pharmacy arrangements"—that is, an *unlimited* number of contract pharmacies, without any geographic limits—"as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition." 75 Fed. Reg. 10,272, 10,273 (2010 Guidance). The 2010 Guidance thus purported to authorize a

covered entity to enter into an unlimited number of contract pharmacy arrangements anywhere in the United States.

32. The 2010 Guidance triggered a massive surge in the number of contract pharmacies receiving and distributing 340B drugs. *See Novartis Pharms.*, 102 F.4th at 457 (noting a "significant expansion"). In 2018, the Government Accountability Office reported that the number of contract pharmacies had ballooned from 1,300 in 2010, to nearly 20,000 in 2017. U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 2 (June 2018) (2018 GAO Report), https://www.gao.gov/assets/700/692697.pdf. These numbers have continued to grow.

33. Today, more than 33,000 different pharmacies participate in the 340B program, with more than 194,000 individual contracts. Adam J. Fein, Drug Channels Inst., *Exclusive: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market* (Jul. 11, 2023), https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html. The vast majority of these contract pharmacies (75% as of 2018) are for-profit retail chain pharmacies; and the five largest national pharmacy chains—CVS, Walgreens, Walmart, Rite-Aid, and Kroger—accounted for a combined 60% of all

340B contract pharmacies, even though these chains represent only 35% of all pharmacies nationwide. 2018 GAO Report at 20-21.

34. Make no mistake, the boom in contract pharmacies has been fueled by the prospect of outsized profit margins on 340B-discounted drugs. As the D.C. Circuit explained:

> While some contract pharmacies maintain separate inventories of section 340B drugs, most fill prescriptions from inventories that intermingle discounted and non-discounted drugs. Only after dispensing the drugs do these pharmacies attempt to discern whether individual customers were patients of covered entities—in other words, whether individual prescriptions were eligible for the discount. Many pharmacies outsource this determination to third-party administrators, who often receive a larger fee for every prescription deemed eligible for the discount. Once the pharmacy or the administrator categorizes a certain number of prescriptions as eligible, the pharmacy places an order to replenish its section 340B purchases. The covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate. Each of these actors thus has a financial incentive to catalog as many prescriptions as possible as eligible for the discount.

Novartis Pharms., 102 F.4th at 457-58; *see* Decl. of Krista M. Pedley ¶¶ 5-9, *Sanofi-Aventis U.S., LLC v. HHS*, No. 3:21-cv-634 (D.N.J. June 24, 2021), ECF No. 93-2.

35. Since a 340B discount is applied for the contract pharmacy sale—even though the sale has *also* benefitted from the full insurance reimbursement—this dynamic results in substantial arbitrage revenues. *See Sanofi*, 58 F.4th at 699 ("[T]hey turn a profit when insurance companies reimburse them at full price for

drugs that they bought at the 340B discount."). And though the pharmacy may share some of its windfall with the covered entity (or the covered entity's vendor), *the patient* has still paid the full out-of-pocket amount designated under his or her insurance policy.

36. As Senator Chuck Grassley put it in a letter to HRSA, for-profit pharmacies "are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients covered by Medicare, Medicaid, or private health insurance in order to maximize their spread." Letter from Sen. Chuck Grassley, S. Comm. on the Judiciary, to Mary K. Wakefield, Adm'r, HRSA (Mar. 27, 2013), https://www.grassley.senate.gov/download/2013-03-27-ceg-to-hrsa-340b-oversight-3. This "spread" means contract pharmacies retain up to $5 billion in annual profits from 340B sales. *See* Neal Masia, *340B Drug Pricing Program: Analysis Reveals $40 Billion in Profits in 2019*, Alliance for Integrity & Reform (May 2021), http://bit.ly/4bM7sHE; Laura Joszt, *340B, Biosimilars, and More in the Future of Specialty Pharmacy*, Am. J. of Managed Care (May 4, 2022), https://bit.ly/4c61Do6 (five contract pharmacies "earn about $3.2 billion in gross profits from 340B"); Walgreens Boots Alliance, Inc., Form 10-K (Oct. 15, 2020), https://bit.ly/3KveDrI (noting that "[c]hanges in pharmaceutical manufacturers' . . . distribution policies . . . in connection with the federal 340B drug pricing program[] could . . . significantly reduce [Walgreens's] profitability");

Rebecca Pifer, *Hospitals, PBMs Say Drugmaker Restrictions on 340B Discounts Stifling Finances*, HealthcareDive (May 5, 2020), https://bit.ly/3P9xmdF (reporting that CVS Health "said its 340B product lines were stagnant" after contract-pharmacy restrictions were imposed).

37. Although some of the money generated through contract pharmacy sales is passed on to covered entities, most of these profits are *not* going to federally qualified health centers or other federal grantees that provide services to underserved populations (such as black lung clinics, hemophilia treatment centers, urban Indian health organizations, and AIDS drug purchasing assistance programs). Instead, they are being captured by 340B hospitals and contract pharmacies, which are responsible for nearly 90% of all 340B purchases. Aaron Vandervelde et al., Berkeley Rsch. Grp., *For-Profit Pharmacy Participation in the 340B Program* 7 (Oct. 2020), https://bit.ly/3owtUwa.

38. Nor are these huge profits being passed on to patients. For example, in response to a 2018 GAO survey, 45% of covered entities admitted they do not pass along *any* discount to *any* patients that use *any* of their contract pharmacies. 2018 GAO Report at 30. As for the remaining 55%, the GAO noted that entities using contract pharmacies may provide discounts to patients only in limited cases. *Id*. Likewise, the HHS Office of Inspector General found in 2014 that some contract pharmacies do not offer 340B-discounted prices to uninsured patients at

all. HHS-OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 2 (Feb. 4, 2014) (2014 OIG Report), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf. As a result, "uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies." *Id.*

39. By contrast, the GAO noted that 17 of 23 of the surveyed covered entities that had *in-house* pharmacies reported offering discounts at those pharmacies. *See* 2018 GAO Report at 30 n.46. Most recently, a report by the Senate Committee on Health, Education, Labor & Pensions found that major covered entities do not directly pass on 340B discounts to patients, with one entity stating to the Committee that "reducing patients' drug expenses is not the purpose of the 340B Program." S. Comm. on Health, Educ., Labor & Pensions, *Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program* 9 (Apr. 2025), https://www.help.senate.gov/imo /media/doc/final_340b_majority_staff_reportpdf.pdf.

40. In short, the widespread proliferation of contract pharmacy arrangements since 2010 has transformed the 340B program from one intended to assist vulnerable patients into a multi-billion-dollar arbitrage scheme.

41. At the same time, the explosive growth of contract pharmacy arrangements also has facilitated increased diversion and duplicate discounts. *See*

Novartis Pharms., 102 F.4th at 458. A 2011 report from the Government Accountability Office warned that "[o]perating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies." U.S. Gov't Accountability Off., GAO-11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 28, (Sept. 23, 2011), https://www.gao.gov/assets/330/323702.pdf. The report further found that "HRSA's oversight of the 340B program is inadequate because it primarily relies on participants' self-policing to ensure compliance." *Id.* at 21.

42. These structural problems have only intensified over time, as the use of multiple contract pharmacies has become rampant. The 2014 OIG report determined that self-policing by covered entities has been insufficient to stop these abuses, since "most covered entities . . . do not conduct all of the oversight activities recommended by HRSA." 2014 OIG Report at 2. The 2018 GAO Report similarly criticized the continuing "weaknesses in HRSA's oversight [that] impede its ability to ensure compliance with 340B Program requirements at contract pharmacies." 2018 GAO Report at 45.

43. Indeed, HRSA's own audits of covered entities continue to identify numerous instances of abuse. The 2018 GAO Report observed that "66 percent of the 380 diversion findings in HRSA audits [between 2012 and 2017] involved

drugs distributed at contract pharmacies." *Id.* at 44. And based on information from HRSA's website, over 25% of covered entities audited since 2017 have had at least one finding related to contract pharmacy noncompliance. Indeed, out of 199 audits conducted in 2019, HRSA discovered dozens of instances of duplicate discounts, as well as evidence that at least 19 covered entities had permitted diversion of 340B drugs through contract pharmacies. *See* HRSA, *Program Integrity: FY19 Audit Results*, https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results.

AstraZeneca's 340B Policy and Resulting Litigation

44. Against this legal and factual backdrop, in August 2020, AstraZeneca announced to covered entities that, effective October 1, 2020, it would revert to the contract pharmacy approach set forth in HRSA's 1996 Guidance.

45. Under this policy, AstraZeneca continues to make its products available at 340B-discounted prices—in unlimited quantities—to all covered entities. For covered entities that do not maintain their own on-site dispensing pharmacy, AstraZeneca offers discounted drugs for sales at a single contract pharmacy site for each covered entity. But AstraZeneca no longer makes 340B discounts available for drugs sold at an unlimited number of contract pharmacies.

46. AstraZeneca's policy is consistent with the letter and intent of the 340B program—limiting the potential for abuse, while still enabling all covered

entities and their patients to continue to access AstraZeneca's medicines at 340B prices. Under AstraZeneca's policy, over 13,000 covered entities that lack an on-site pharmacy have registered a contract pharmacy to which AstraZeneca continues to make 340B discounts available, including numerous covered entities in Hawaii. AstraZeneca is committed to working with all covered entities to ensure that all patients can obtain needed medicines at prices they can afford.

47. In response to AstraZeneca's new contract pharmacy policy and other manufacturers' adoption of similar policies, HHS and HRSA issued an Advisory Opinion on December 30, 2020, asserting that the 340B statute requires manufacturers to offer 340B-discounted drugs for sales at unlimited contract pharmacies.

48. In early 2021, AstraZeneca filed suit in the U.S. District Court for the District of Delaware against HHS and HRSA, challenging the Advisory Opinion. On June 16, 2021, the Delaware court issued a detailed opinion finding the Advisory Opinion unlawful. *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47 (D. Del. 2021). The court concluded that Section 340B "says nothing about the permissible role (if any) of contract pharmacies," and that, in light of this "total omission," the Advisory Opinion's attempt to impose an obligation on AstraZeneca to make discounted drugs available for sales at unlimited contract

pharmacies was "legally flawed." *Id.* at 59. The agency withdrew the Advisory Opinion following the Delaware court's ruling.

49. In a second ruling, the Delaware court addressed AstraZeneca's challenge to a "violation letter" issued by HRSA, which adopted the same position as the Advisory Opinion. The court again rejected the agency's view that Section 340B obligates drug manufacturers to make 340B-discounted drugs available for unlimited contract pharmacy sales. *AstraZeneca Pharms. LP v. Becerra*, No. 21-cv-27, 2022 WL 484587 (D. Del. Feb. 16, 2022). The court reiterated "key points" from its prior opinion, including that Congress "did not clearly intend for drug manufacturers to be required to facilitate sales of covered drugs for dispensing by an unlimited number of contract pharmacies." *Id.* at *5-*6.

50. On January 30, 2023, the U.S. Court of Appeals for the Third Circuit affirmed the Delaware court's rulings. In a consolidated opinion addressing AstraZeneca's case and appeals in parallel actions by other manufacturers, the Third Circuit held that the Advisory Opinion and violation letter are "unlawful," and it "enjoin[ed] HHS from enforcing [it] against" AstraZeneca. *Sanofi*, 58 F.4th at 706. The court of appeals also held that AstraZeneca's policy of not offering discounts for sales at unlimited "contract pharmacies do[es] not violate Section 340B." *Id.*

51. The government neither sought en banc review of the Third Circuit's decision nor filed a petition for certiorari in the U.S. Supreme Court.

52. On May 5, 2023, the Delaware court issued a final judgment in AstraZeneca's case, to which the government stipulated. The court's order provides that it is:

a. "DECLARED that Advisory Opinion 20-06 and the Violation Letter from the Health Resources and Services Administration to Plaintiff AstraZeneca Pharmaceuticals LP (AstraZeneca), dated May 17, 2021 (Violation Letter), are unlawful;

b. DECLARED that AstraZeneca's policy limiting the use of contract pharmacies under Section 340B of the Public Health Service Act (Section 340B), 42 U.S.C. § 256b—namely, that covered entities may use an in-house pharmacy and, if they do not have an in-house pharmacy, they may use one contract pharmacy—does not violate Section 340B;

c. ORDERED that the Violation Letter is VACATED as contrary to law pursuant to 5 U.S.C. § 706;

d. ORDERED that Defendants, including their officers, agents, and employees, are ENJOINED from enforcing against AstraZeneca the agency's reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies."

Final Judgment at 1, *AstraZeneca*, No. 1:21-cv-27 (D. Del. May 5, 2023), ECF No. 123.

53. As a result of the Third Circuit's ruling and the Delaware court's injunction, AstraZeneca is entitled to proceed with its lawful contract pharmacy policy.

Hawaii Enacts Legislation Requiring Manufacturers to Make 340B-Discounted Drugs Available for Unlimited Contract Pharmacy Sales

54. On April 30, 2025, the Hawaii Legislature passed Act 143, which Governor Josh Green signed into law on May 30, 2025.

55. The law took effect on July 1, 2025. Act 143 § 3.

56. Act 143 provides that "[n]o drug manufacturer, or any agent or affiliate of a 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 340B covered entity unless the receipt is prohibited by the United States Department of Health and Human Services." *Id.* § 2-2(a). This provision does not identify a geographical limit to its coverage.

57. Act 143 defines its basic terms by reference to federal law. It defines "340B drug" to mean "a prescription drug that is purchased by a 340B covered entity through the federal 340B drug pricing program authorized by title 42 United

States Code section 256b (section 340B of the Public Health Service Act) and is dispensed by a pharmacy." Act 143 § 2-1. It defines "340B covered entity" to mean "an entity that participates in the federal 340B drug pricing program authorized by title 42 United States Code section 256b (section 340B of the Public Health Service Act).

58. Act 143 does not prohibit diversion or otherwise require that drugs purchased at 340B-discounted prices be dispensed only to patients of a covered entity. *See* 42 U.S.C. § 256b(a)(5)(B) ("[A] covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."). Nor does the Act account for HRSA's enforcement authority or for the congressionally mandated procedures for administrative dispute resolution. *See id.* § 256b(d)(3).

59. Act 143 empowers the Hawaii Attorney General to "bring a civil action to enjoin" an alleged violation of the statute. Act 143 § 2-4(a). The statute also creates a private right of action under which any covered entity may seek to enjoin alleged violations of the statute resulting in injury to the covered entity's "business or property." *Id.* § 2-3.

60. A violation of Act 143 is punishable by a fine of up to $2,500 per violation, and "[e]ach day that a violation … occurs shall constitute a separate violation." *Id.* § 2-4(b). Fines are collected through civil enforcement actions brought by the Attorney General, in which the court may also award

"disgorgement and any other equitable relief that it considers appropriate." *Id.* § 2-4(c).

LEGAL ALLEGATIONS

Act 143 Is Preempted by Section 340B

61. The Supremacy Clause of the U.S. Constitution provides that the "Constitution, and the Laws of the United States which shall be made in Pursuance thereof," are "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. The doctrine of federal preemption that arises out of the Supremacy Clause requires that "any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Harding v. Galceran*, 889 F.2d 906, 908 (9th Cir. 1989) (quoting *Felder v. Casey*, 487 U.S. 131, 138 (1988)).

62. Act 143 "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *United States v. California*, 921 F.3d 865, 879 (9th Cir. 2019) (quoting *Arizona v. United States*, 567 U.S. 387, 399 (2012)). Its mandates for drug manufacturers and the associated enforcement mechanisms are preempted by the 340B statute under the Supremacy Clause.

63. The operation and apparent intent of Act 143 is to compel pharmaceutical manufacturers to make 340B discounts available for unlimited contract pharmacy sales, despite the Third and D.C. Circuits' holdings that federal

law imposes no such requirement, and notwithstanding the Delaware court's injunction.

64. Although it uses the words "acquisition" and "delivery," Act 143 does not actually regulate drug distribution; instead, it regulates access to 340B *discounts*. The law directly regulates "340B drug[s]," defined to mean "a prescription drug that is purchased by a 340B covered entity through the federal 340B drug pricing program authorized by title 42 United States Code section 256b (section 340B of the Public Health Service Act) and is dispensed by a pharmacy." Act 143 § 2-1.

65. By prohibiting manufacturers from restricting the access of covered entities to 340B-discounted drugs, Act 143 on its face regulates pricing—and insofar as manufacturers are affected, *only* regulates pricing. In requiring manufacturers to provide access to "340B drugs," the statute confers access to *prices* that have been reduced under the statutory formula prescribed by Section 340B.

66. The statute does not affect any other aspect of the acquisition or delivery of drugs—such as packaging requirements, shipping conditions, shipping costs, or other logistics and specifications of drug delivery and acquisition. To the contrary, pricing is the *only* thing that distinguishes a sale that complies with Act 143 from a sale that violates Act 143.

67. By extending 340B pricing to unlimited contract pharmacy sales—thereby drastically increasing manufacturers' costs of participating in the 340B program—Act 143 impermissibly interferes with important federal policies and objectives. Prior to the law's enactment, manufacturers were obligated to offer 340B discounts for sales directly to covered entities themselves, which they used to "turn a profit" on sales mandated by the 340B program. *Sanofi*, 58 F.4th at 699.

68. But Act 143 imposes costly new obligations on top of that; it also requires manufacturers to offer 340B discounts for an additional category of transactions as well: contract pharmacy sales. Doing so may enable covered entities and their associated contract pharmacies to "squeeze [more] revenue out of" the program. *Id.* at 704. But it imposes a corresponding cost on manufacturers, significantly increasing the burdens of participating in a federal program.

69. In effect, Hawaii has used manufacturers' participation in the federal 340B program as leverage to extract additional money from them under state law. The result is to "exert an extraneous pull on the scheme established by Congress," thus "skew[ing]" the "delicate balance of statutory objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348, 353 (2001).

70. Even if Act 143 could somehow be construed as regulating delivery, rather than regulating pricing, that *still* would not save it from preemption.

Imposing a costly new delivery obligation on transactions under a federal program just as readily "discourage[s]" participation in the program. *Id.* at 350.

71. In addition, the Supremacy Clause prohibits States from establishing parallel regimes that encroach on the federal government's authority to set and define federal enforcement priorities. *See id.* at 349-51.

72. Act 143 directly interferes with the robust federal enforcement regime that Congress has enacted for the 340B program, which includes the ADR process, required auditing provisions for manufacturers and covered entities, and the possibility of civil monetary penalties in the event of a manufacturer overcharge or diversion by a covered entity.

73. Act 143 interferes with enforcement of the 340B program in another respect: It requires state officials to adjudicate disputes about the meaning and application of federal terms and provisions.

74. Act 143 enables both the Hawaii Attorney General and covered entities to "bring a civil action to enjoin" violations of the statute. Act 143 §§ 2-3, 2-4.

75. In any state enforcement proceeding, a state adjudicator would be required to consider and resolve questions of federal law in order to determine whether a manufacturer has violated Act 143. Among other things, the adjudicator would need to decide whether the 340B drugs to which the manufacturer allegedly

denied or restricted access were intended for a "a patient of the entity," as required for eligibility under the 340B program. 42 U.S.C. § 256b(a)(5)(B). That question turns on the definition of "patient of the entity" under federal law.

76. The adjudicator would also be required to determine whether a particular covered entity continues to qualify for participation in the 340B program, which depends on whether the entity sells or transfers 340B-drugs to anyone other than its patients or seeks duplicate discounts. *See id.* § 256b(a)(4) (defining "'covered entity'" to "mean[] an entity that meets the requirements described in paragraph (5)," which includes the prohibitions on diversion and duplicate discounts). These issues are often disputed and have been the subject of federal litigation. *See, e.g.*, *Amgen Inc. v. Becerra*, No. 1:24-cv-3571 (D.D.C. filed Dec. 20, 2024).

77. In *Astra USA, Inc. v. Santa Clara County*, the Supreme Court held that private entities may not bring actions under state contract law to enforce the provisions of manufacturers' 340B pharmaceutical pricing agreements. 563 U.S. at 113-14. "Congress made HHS administrator of … the 340B Program." *Id.* at 120. Suits by private entities, the Court explained, "would undermine the agency's efforts" to administer the program "harmoniously and on a uniform, nationwide basis." *Id.* "With HHS unable to hold the control rein, the risk of conflicting adjudications would be substantial." *Id.*

78. Act 143 makes that risk unavoidable. By inserting Hawaii and its officials into the program that Congress adopted, the law frustrates the accomplishment of Congress's objectives and interferes with Congress's chosen method of oversight.

Act 143 Is Preempted by Federal Patent Law as Applied to AstraZeneca's Patented Products

79. As applied to AstraZeneca's patented products, Act 143 is also preempted by the federal patent laws because it regulates the prices at which patented drugs may be sold.

80. The Constitution gives Congress exclusive authority to establish a system of incentives "[t]o promote the Progress of Science and useful Arts." Art. I, § 8, cl. 8. Under the federal patent law, inventors are "impelled to invest in creative effort" on the promise that they will obtain "a federally protected 'exclusive right'" to sell their inventions for a limited period. *BIO*, 496 F.3d at 1372. The public can benefit from immediate access to new inventions during the exclusivity period; and after the period expires, the public gets "lower price[s] through unfettered competition." *Id.* at 1373. The States are not free to upset that finely calibrated system: "Where it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989).

81. State laws that cap or fix the prices at which patented drugs may be sold are accordingly preempted by federal patent law, as the Federal Circuit has explained, because they "re-balance the statutory framework of rewards and incentives . . . in effect diminishing the reward to patentees in order to provide greater benefit to . . . drug consumers." *BIO*, 496 F.3d at 1374. In *BIO*, the Federal Circuit struck down a District of Columbia law that prohibited patented drugs from "being sold in the District for an excessive price." *Id.* at 1365. The court explained that, notwithstanding "the District's judgment" that drug manufacturers were charging "excessive prices" that "threaten[ed] the health and welfare of the residents of the District as well as the District government's ability to ensure that all residents receive the health care they need," the law was "contrary to the goals established by Congress in the patent laws." *Id.* at 1365, 1374 (quoting D.C. Code § 28-4551). The District's law was therefore preempted because "[t]he underlying determination about the proper balance between innovators' profit and consumer access to medication . . . is exclusively one for Congress to make." *Id.* at 1374.

82. The same analysis applies to Act 143. Like the District of Columbia law invalidated in *BIO*, Act 143 restricts the prices at which manufacturers must offer their patented drugs by requiring them to make 340B discounts available for unlimited contract pharmacy sales. Whereas Section 340B caps drug prices with

respect to a manufacturer's offer to sell its drugs to a limited set of specifically enumerated covered entities, Act 143 purports to extend those price caps to a category of sales—unlimited contract pharmacy sales—where federal courts have held that manufacturers are *not* required to offer them under the federal program. Accordingly, the Act functions as a price cap for unlimited contract pharmacy sales, impermissibly constraining manufacturers' "opportunity" to take advantage of the benefit of exclusivity conferred by Congress "during the patent's term." *Id.* at 1372.

83. Act 143 is thus preempted by federal patent law as applied to AstraZeneca's patented products. States are not permitted to set the prices of patented drugs or to "re-balance" the "rewards and incentives" embodied in the federal patent laws, as Hawaii has done here. *Id.* at 1374.

Act 143 Violates the Contracts Clause

84. Act 143 also violates the Contracts Clause of the U.S. Constitution. Article I, section 10, clause 1 of the Constitution provides that "No State shall . . . pass any . . . Law impairing the Obligation of Contracts." Courts have interpreted the Contracts Clause to require "a three-step inquiry" to balance the State's obligation not to impair contracts with the State's interest in public welfare. *RUI One Corp. v. City of Berkeley*, 371 F.3d 1137, 1147 (9th Cir. 2004). First, the court asks "whether the state law has, in fact, operated as a substantial impairment

of a contractual relationship." *Id.* (quoting *Energy Rsrvs. Grp., Inc. v. Kan. Power & Light Co.*, 459 U.S. 400, 411 (1983)). Second, if the court finds substantial impairment, it must examine whether the State has a "significant and legitimate public purpose behind the regulation." *Id.* (quoting *Energy Rsrvs. Grp.*, 459 U.S. at 411). Third, if the State presents a legitimate justification for the impairment, the court must determine "whether the adjustment of the rights and responsibilities of contracting parties is based upon reasonable conditions and is of a character appropriate to the public purpose justifying the legislation's adoption." *Id.* (quoting *Energy Rsrvs. Grp.*, 459 U.S. at 412).

85. Act 143 fails at every stage of this test. Act 143 substantially impairs a contractual relationship. As explained above, the 340B program operates through contracts, which are called pharmaceutical pricing agreements (PPAs). PPAs are "uniform agreements that recite the responsibilities § 340B imposes . . . on drug manufacturers and the Secretary of HHS." *Astra USA*, 563 U.S. at 113. While PPAs are not "transactional, bargained-for contracts," *id.*, they nonetheless announce the parties' rights and obligations like any other contract, and manufacturers like AstraZeneca are entitled to rely on the PPA's terms when developing their business. Among those terms is the requirement that manufacturers offer discounted drugs only for sales to a specifically delineated set of "covered entities." As the Third Circuit held, and the D.C. Circuit later

underscored, neither the 340B statute nor the PPA requires AstraZeneca to make 340B discounts available for sales at "an unlimited number of contract pharmacies." *Novartis Pharms.*, 102 F.4th at 461 (quoting *Sanofi Aventis*, 58 F.4th at 706).

86. Act 143 operates as a substantial impairment of AstraZeneca's PPA with the HHS Secretary. AstraZeneca joined the 340B program with the expectation and understanding that it would be required to offer discounts only for a limited category of sales, and it accepted that obligation. The Act seeks to unilaterally expand AstraZeneca's obligations under that contract—without AstraZeneca's consent—by requiring AstraZeneca to offer discounts for an entirely new category of sales: contract pharmacy sales.

87. The U.S. Supreme Court has held that similar expansions of beneficiaries to a contract constitute substantial impairment under the Contracts Clause. *See Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234, 245-46 (1978) (Contracts Clause prohibited State from requiring company to provide additional pension benefits after it had agreed to provide pension benefits under specific contractual conditions); *see also United Healthcare Ins. Co. v. Davis*, 602 F.3d 618, 630 (5th Cir. 2010) (Contracts Clause prohibited state from enacting legislation increasing obligations on companies that had agreed to insure state employees under specific conditions).

88. Any justification Hawaii might offer for Act 143 would be insufficient under the Contracts Clause. Hawaii cannot claim that its law is necessary to provide access to 340B drugs to covered entities and their patients, because AstraZeneca's policy already ensures that every covered entity is offered those drugs at a discounted price. Indeed, AstraZeneca's policy goes further, allowing covered entities to designate a single contract pharmacy if it does not have an on-site pharmacy.

89. Hawaii has no legitimate justification for requiring discounts for unlimited contract pharmacy sales, which will advance the economic interests of for-profit entities at the expense of companies like AstraZeneca, particularly where Congress itself has not required them.

90. Nor can Hawaii justify Act 143 as a cost-reduction mechanism for patients. Nothing in the Act requires that discounts must be passed on to patients, and in fact studies show that most 340B discounts to contract pharmacies are *not* passed on to patients, who must pay full price for their drugs. *See* ¶ 33, *supra*.

91. Finally, even if Hawaii could articulate a legitimate justification for Act 143's impairment of AstraZeneca's PPA, that justification would not be reasonable and necessary to achieve the State's goals.

Act 143 Violates the Takings Clause

92. The Takings Clause of the U.S. Constitution provides that "private property" may not "be taken for public use, without just compensation." U.S. Const. amend. V.

93. Under the Takings Clause, although the government may take private property "for public use" so long as it pays "just compensation," the government may never take private property for *private* use, regardless of the amount of compensation paid. As the U.S. Supreme Court has explained, "the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*," a prohibition that applies regardless of whether "*A* is paid just compensation." *Kelo*, 545 U.S. at 477. Such takings for private use are always unlawful, since "[n]o amount of compensation can authorize such action." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005).

94. Act 143 takes the private property of manufacturers like AstraZeneca for private, not public, use. The law forces manufacturers to transfer their prescription drugs to other private (non-governmental) entities—namely, to covered entities and the pharmacies with which they contract—at prices that AstraZeneca would not otherwise offer (and is not required to offer under federal law).

95. This forced transfer would be unlawful even if manufacturers were paid just compensation for these contract pharmacy sales. *See id.* But manufacturers are *not* justly compensated for the forced transfers covered by the law: The law requires manufacturers to make these transfers at steeply discounted prices, well below fair market value.

96. This forced transfer results in the "physical appropriation" of manufacturers' prescription drugs by contract pharmacies and covered entities, and it therefore constitutes "a *per se* taking." *Cedar Point Nursery v. Hasid*, 594 U.S. 139, 149 (2021).

97. But even if Act 143 did not involve a physical appropriation, it would still constitute a regulatory taking because it (1) has a profound economic impact on the value of the property subject to the law; (2) significantly interferes with manufacturers' investment-backed expectations; and (3) forces manufacturers to transfer title to their property, depriving them of the full use and enjoyment of that property. *See Penn Central Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978).

98. Act 143 accordingly violates the Takings Clause of the U.S. Constitution.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – Act 143 is Preempted by Section 340B Supremacy Clause, U.S. Const. art. VI, cl. 2)

99. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

100. The Supremacy Clause, U.S. Const. art. VI, cl. 2, prohibits a State from enacting any law "which interferes with or is contrary to federal law," *Harding* 889 F.2d at 908 (quoting *Felder*, 487 U.S. at 138). The mandates imposed on drug manufacturers by Act 143, and its associated enforcement mechanisms, are preempted by the 340B statute under the Supremacy Clause.

101. Act 143 creates an obstacle to the accomplishment and execution of Congress's objectives for the 340B statute. It imposes significant new costs for participating in a federal benefits program, thereby "exert[ing] an extraneous pull on the scheme established by Congress" and "skew[ing]" the "delicate balance of statutory objectives." *Buckman*, 531 U.S. at 348, 353. In addition, Section 340B includes a comprehensive regime for enforcement and management of the program, which includes the ADR process, audits, and civil monetary penalties. Act 143's attempt to insert into Congress's program a layer of enforcement by state officials under Hawaii law frustrates Congress's purposes and interferes with the carefully specified federal regime it created.

102. For these reasons, Act 143's provisions requiring manufacturers to offer 340B discounts for unlimited contract pharmacy sales, and empowering Defendant and covered entities to pursue purported violations of the statute, are preempted by federal law under the Supremacy Clause.

SECOND CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – Act 143 is Preempted by Federal Patent Law Supremacy Clause, U.S. Const. art. VI, cl. 2)

103. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

104. The Supremacy Clause, U.S. Const. art. VI, cl. 2, prohibits a State from enacting any law "which interferes with or is contrary to federal law." *Harding*, 889 F.2d at 908 (quoting *Felder*, 487 U.S. at 138). Moreover, the Constitution assigns exclusive authority to regulate patents to the U.S. Congress. With respect to pharmaceuticals, Congress has enacted comprehensive legislation establishing the scope of patent rights under federal law. Thus, state laws that cap or fix drug prices are preempted by federal patent law because they "re-balance the statutory framework of rewards and incentives . . . in effect diminishing the reward to patentees in order to provide greater benefit to . . . drug consumers." *BIO*, 496 F.3d at 1374.

105. Act 143 requires manufacturers to make 340B discounts available for unlimited contract pharmacy sales, and it empowers Defendant to pursue purported

violations of the statute. As applied to AstraZeneca's patented products, those provisions are preempted by federal patent law under the Supremacy Clause.

106. The obligation imposed by Act 143 on manufacturers—to offer 340B discounts for unlimited contract pharmacy sales—caps the prices at which manufacturers can sell their patented drugs and constrains manufacturers' "opportunity" to take advantage of the benefits of exclusivity "during the patent's term." *Id.* at 1372. The Act therefore impermissibly seeks to "re-balance" the "rewards and incentives" embodied in the federal patent laws in a manner that is beyond a state's powers. *Id.* at 1374. Act 143 is therefore preempted by federal patent law under the Supremacy Clause as applied to AstraZeneca's patented products.

THIRD CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – Act 143 Violates the Contracts Clause, U.S. Const. art. I, § 10, cl. 1)

107. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

108. Under the Contracts Clause, U.S. Const. art. I, § 10, cl. 1, "[n]o State shall . . . pass any . . . Law impairing the Obligation of Contracts." The Contracts Clause thus prohibits States from enacting legislation that "operate[] as a substantial impairment of a contractual relationship." *RUI One Corp.*, 371 F.3d at 1147 (quoting *Energy Rsrvs. Grp.*, 459 U.S. at 411).

109. Act 143 violates the Contracts Clause. It substantially impairs AstraZeneca's PPA with the HHS Secretary by requiring AstraZeneca to offer 340B discounts for unlimited contract pharmacy sales, thus purporting to substantially expand AstraZeneca's obligations under the agreement beyond what the agreement itself provides.

110. Hawaii has no valid justification for impairing AstraZeneca's PPA. AstraZeneca's policy ensures that every covered entity is offered 340B drugs at statutorily required prices. The policy also allows covered entities without an on-site pharmacy to utilize a single contract pharmacy, which is more than the statute requires. Compelling AstraZeneca to provide 340B-discounted drugs for unlimited contract pharmacy sales advances the economic interests of for-profit pharmacies at AstraZeneca's expense, with little to no benefit to 340B patients.

111. Even if Hawaii could identify a legitimate justification for impairing AstraZeneca's PPA, it would not be reasonable and necessary to achieve the State's goals.

112. Act 143 is also unconstitutional under the Contracts Clause to the extent it requires AstraZeneca to offer 340B discounts for sales at contract pharmacies that do not qualify as covered entities, and which therefore are not included within the anticipated or actual scope of the PPA that AstraZeneca signed with the HHS Secretary.

FOURTH CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – Act 143 Violates the Takings Clause, U.S. Const., amend. V)

113. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

114. Under the Takings Clause of the Fifth Amendment of the U.S. Constitution, the government may not take "private property" for private use—such as requiring the transfer of ownership from one private party to another—even if just compensation is paid.

115. Act 143 takes private property for private use by forcing manufacturers to transfer 340B-discounted drugs—including relinquishing title and control of the drugs—to private, non-governmental entities (covered entities and their contract pharmacies) at non-commercial prices that AstraZeneca would not otherwise offer.

116. Act 143 also denies manufacturers just compensation because it requires that their drugs be transferred to these private entities at below-market prices.

117. The forced transfer of drugs under Act 143 constitutes a taking per se or, in the alternative, a regulatory taking.

118. Act 143 is therefore unconstitutional under the Takings Clause.

PRAYER FOR RELIEF

NOW, THEREFORE**,** AstraZeneca requests a judgment in its favor against the Hawaii Attorney General as follows:

A. Declare that Act 143 is preempted by Section 340B and is therefore null, void, and unenforceable;

B. Declare that Act 143 is preempted by federal patent law, and therefore null, void, and unenforceable, as applied to AstraZeneca's patented products;

C. Declare that Act 143 is unconstitutional as applied to AstraZeneca under the Contracts Clause of the U.S. Constitution;

D. Declare that Act 143 is unconstitutional as applied to AstraZeneca under the Takings Clause of the U.S. Constitution;

E. Declare that AstraZeneca is not required to offer 340B discounts for unlimited contract pharmacy sales under Hawaii law;

F. Issue preliminary and permanent injunctive relief preventing Defendant from implementing or enforcing Act 143 against AstraZeneca or any of its affiliates, officers, agents, or contractors;

G. Issue preliminary and permanent injunctive relief preventing Defendant from seeking civil penalties, equitable relief, or any other

remedy based on any alleged violation of Act 143 by AstraZeneca or any of its affiliates, officers, agents, or contractors;

H. Award AstraZeneca reasonable attorneys' fees and costs, as appropriate; and

I. Grant such other and further relief as the Court may deem appropriate.

DATED: Honolulu, Hawaii, August 29, 2025.

/s/ Brett R. Tobin
DAVID J. MINKIN
BRETT R. TOBIN

Attorneys for Plaintiff
ASTRAZENECA PHARMACEUTICALS LP