

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF HAWAI‘I

AstraZeneca Pharmaceuticals LP v. Anne E. Lopez

AstraZeneca Pharmaceuticals LP v. Lopez, Civil No. 25-00369 MWJS-WRP (D. Haw. Feb. 23, 2026) · No. Civil No. 25-00369 MWJS-WRP · Decided February 23, 2026

SUMMARY

The United States District Court for the District of Hawai‘i denied AstraZeneca Pharmaceuticals LP’s motion for a preliminary injunction against enforcement of Hawai‘i Act 143. The court concluded that AstraZeneca had not shown a likelihood of success, or serious questions going to the merits, on its claims that Act 143 was preempted by the federal Section 340B drug-pricing program or federal patent law. The order addresses whether Act 143 regulates drug pricing or delivery conditions and applies the federal preliminary-injunction standard.

CASE DETAILS

COURT	United States District Court for the District of Hawai‘i
WRITING FOR THE COURT	Micah W.J. Smith
JURISDICTION	United States District Court for the District of Hawai‘i
DECIDED	February 23, 2026
DOCKET	Civil No. 25-00369 MWJS-WRP
DISPOSITION	other
PROCEDURAL POSTURE	AstraZeneca sought a preliminary injunction against enforcement of Hawai‘i Act 143 while pursuing federal preemption claims. The court denied the motion; the State’s motion to dismiss remained pending for resolution by separate order.
STANDARD OF REVIEW	A preliminary injunction requires a clear showing of a likelihood of success on the merits, or at least serious questions going to the merits, a likelihood of irreparable harm, a favorable balance of equities, and consistency with the public interest. Likelihood of success is a threshold and most important inquiry; failure to satisfy it permits denial without reaching the remaining factors.
PRECEDENTIAL VALUE	Nonprecedential district-court interlocutory order
PARTIES	AstraZeneca Pharmaceuticals LP v. Anne E. Lopez, Attorney General of the State of Hawai‘i

TOPICS

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QUESTIONS PRESENTED

1. Whether AstraZeneca was entitled to a preliminary injunction based on its claim that Hawai‘i Act 143 is preempted by Section 340B through obstacle or purposes-and-objectives preemption.
2. Whether the presumption against preemption applies to Act 143.
3. Whether Act 143 regulates drug pricing rather than delivery conditions.
4. Whether Act 143 is preempted under intergovernmental-immunity principles as a direct regulation of federal contractors.
5. Whether Act 143 is preempted by federal patent law because it allegedly diminishes the economic rewards or incentives associated with AstraZeneca’s patents.

HOLDINGS

1. AstraZeneca was not entitled to a preliminary injunction because it failed to demonstrate a likelihood of success on the merits or serious questions going to the merits of its preemption claims.
2. At the preliminary-injunction stage, Act 143 is properly characterized as regulating delivery and availability of 340B drugs, not the federally established price of those drugs.
3. The presumption against preemption applies to Act 143 because the statute regulates drug delivery and access in an area involving traditional state public-health and safety powers, even though it operates only within the Section 340B program.
4. AstraZeneca failed to show a likelihood of success or serious questions that Act 143 is an obstacle to the purposes and objectives of Section 340B.
5. AstraZeneca failed to show that Act 143 is preempted by federal patent law because the statute regulates commercial delivery terms without authorizing copying, compulsory licensing, or interference with the patent holder’s exclusionary right.

KEY QUOTATIONS

“A preliminary injunction is an extraordinary form of relief, which a court may not lightly grant.”
(Conclusion, PageID.1041)

“In short, price governs the economic terms of exchange; delivery governs access.” (Discussion Part A)

“The bottom line is that “congressional and regulatory silence usually defeats a claim of preemption, not the other way around.”” (Discussion Part C.2)

“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.” (Discussion Part D)

FACTUAL BACKGROUND

Section 340B of the Public Health Service Act requires participating drug manufacturers to offer covered outpatient drugs to qualifying covered entities at or below statutory ceiling prices. After HRSA expanded contract-pharmacy arrangements and manufacturers began imposing restrictions on delivery of 340B drugs through contract pharmacies, Hawai‘i enacted Act 143, which prohibits manufacturers from denying, restricting, or prohibiting acquisition, shipping, or delivery of 340B drugs to authorized contract pharmacies. AstraZeneca maintained restrictions on contract-pharmacy shipments and argued that Act 143 was preempted by Section 340B and federal patent law.

PROCEDURAL HISTORY

AstraZeneca filed an action challenging Hawai‘i Act 143 on federal preemption, Contracts Clause, and Takings Clause grounds. It moved for a preliminary injunction limited to its preemption claims. After permitting limited expedited discovery and supplemental briefing, the court held a hearing on February 9, 2026, and denied preliminary relief because AstraZeneca failed to show a likelihood of success on the merits or serious questions going to the merits.

DISPOSITION

other

CASES CITED

- *Lopez v. Brewer*, 680 F.3d 1068, 1072 (9th Cir. 2012)
- *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam)
- *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008)
- *Garcia v. Google, Inc.*, 786 F.3d 733, 740 (9th Cir. 2015) (en banc)
- *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134-35 (9th Cir. 2011)
- *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 372-73 (2000)
- *Wyeth v. Levine*, 555 U.S. 555, 563-65, 578-79 (2009)
- *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.*, 48 F.4th 1040, 1045, 1048 (9th Cir. 2022)
- *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 703-04, 706 (3d Cir. 2023)
- *Novartis Pharmaceuticals Corp. v. Johnson*, 102 F.4th 452, 455-64 (D.C. Cir. 2024)
- *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113, 121 (2011)
- *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341, 343, 347-49 (2001)
- *English v. General Electric Co.*, 496 U.S. 72, 76-90 (1990)
- *City of Los Angeles v. AECOM Services, Inc.*, 854 F.3d 1149, 1160 (9th Cir. 2017)

- Chamber of Commerce of the United States v. Whiting, 563 U.S. 582, 607-10 (2011)
- Planned Parenthood of Indiana, Inc. v. Commissioner of Indiana State Department of Health, 699 F.3d 962, 985 (7th Cir. 2012)
- United States v. Washington, 596 U.S. 832, 836, 838-39 (2022)
- McCulloch v. Maryland, 17 U.S. 316, 436 (1819)
- United States v. County of Fresno, 429 U.S. 452, 460 (1977)
- Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 152 (1989)
- Biotechnology Industry Organization v. District of Columbia, 496 F.3d 1362, 1372-74 (Fed. Cir. 2007)
- Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 230-31 (1964)
- Kimble v. Marvel Entertainment, LLC, 576 U.S. 446, 451 (2015)
- Pfizer, Inc. v. Heckler, 735 F.2d 1502, 1513 (D.C. Cir. 1984)
- AstraZeneca Pharmaceuticals LP v. Becerra, 543 F. Supp. 3d 47, 52-53
- AstraZeneca Pharmaceuticals LP v. McClain, No. 4:24-cv-268-KGB, 2025 WL 4092197, at *7 (E.D. Ark. Sept. 30, 2025)