IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION

ASTRAZENECA PHARMACEUTICALS LP **PLAINTIFF**

v. **Case No. 4:24-cv-00268-KGB**

JIMMY HARRIS, in his official capacity as Commissioner of the Arkansas Insurance Department **DEFENDANT**

DALLAS COUNTY MEDICAL CENTER **INTERVENOR**

OPINION AND ORDER

Pending before the Court are intervenor Dallas County Medical Center's ("DCMC"), motion to compel discovery (Dkt. No. 91) and plaintiff AstraZeneca Pharmaceuticals LP's ("AstraZeneca") response to the motion (Dkt. No. 135). Also before the Court are AstraZeneca's motion for summary judgment (Dkt. No. 131), and the Arkansas Insurance Department Commissioner ("AID") and DCMC's cross-motion for summary judgment (Dkt. No. 136). The parties have responded and replied to the pending motions.[1] For the following reasons, the Court denies as moot the motion to compel (Dkt. No. 91), denies AstraZeneca's motion for summary judgment (Dkt. No. 131), and grants AID and DCMC's cross-motion for summary judgment (Dkt. No. 136).[2]

[1] In reviewing and ruling on the pending motions, the Court has considered all of the parties' filings, including but not limited to the following:

(1) AstraZeneca's opposition to AID and DCMC's motion for summary judgment (Dkt. No. 144).

(2) AstraZeneca's reply in support of its motion for summary judgment and response to AID and DCMC's cross-motion for summary judgment (Dkt. No. 146).

(3) AID and DCMC's reply in support of their cross-motion for summary judgment (Dkt. No. 153).

[2] In reviewing and ruling on the pending motions, the Court has considered all of the parties' filings, including but not limited to those intended to notify the Court of supplemental authority and the responses to those filings (Dkt. Nos. 155–158; 162–164; 166–173).

I. Background[3]

This case arises out of the Arkansas legislature's passage of Act 1103 of 2021 ("Act 1103"), Arkansas Code Annotated § 23-92-601 *et seq*., which set rules for the delivery of Section 340B drugs to contract pharmacies in Arkansas. Section 340B is a federal prescription drug program that requires pharmaceutical manufacturers to provide qualified health care providers, referred to as "covered entities," with pricing discounts on certain drugs prescribed to individuals and families whose income falls below the federal poverty level. 42 U.S.C. § 256b(a)(l); 42 U.S.C. § 1396r-8(a)(l). Covered entities have contracted with outside pharmacies ("contract pharmacies") for the distribution of 340B drugs. Act 1103 addresses drug manufacturers' restrictions on the number of contract pharmacies a covered entity can use and still receive discount pricing under a Section 340B plan. Ark. Code Ann. § 23-92-60.

Section 340B requires pharmaceutical manufacturers that want the federal government to cover their drugs under Medicaid and Medicare Part B to provide discounts on their drugs to certain healthcare providers. 42 U.S.C. §§ 256b, 1396r-8(a)(1), (5); *see Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023), judgment entered, Case No. 21-3167, 2023 WL 1325507 (3d Cir. Jan. 30, 2023). Covered entities include public hospitals and community health centers, many of which are "providers of safety-net services to the

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[3] In reviewing an ruling on the pending motions, the Court has viewed the record evidence in the light of the nonmoving party. Further, the Court has considered the parties' filings, including but not limited to the following:

(1) AID and DCMC's statement of undisputed material facts and facts supporting their response to AstraZeneca's statement of undisputed material facts (Dkt. No. 138).
(2) AID and DCMC's response to AstraZeneca's statement of material facts not in dispute (Dtk. No. 139).
(3) AstraZeneca's objections and responses to AID and DCMC's statement of undisputed material facts (Dkt. No. 145).
(4) AstraZeneca's reply in support of its statement of undisputed material facts (Dkt. No. 147).
(5) AID and DCMC's reply in support of their statement of undisputed material facts and facts supporting response to AstraZeneca's statement of undisputed material facts (Dkt. No. 154).

poor." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011). The 340B Program "is superintended by the Health Resources and Services Administration" ("HRSA"), "a unit of the Department of Health and Human Services" ("HHS"). *Astra*, 563 U.S. at 113.

"Drug manufacturers," such as AstraZeneca, "opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement" ("PPA") "used nationwide." *Id.* These agreements "are not transactional, bargained-for contracts. They are uniform agreements that recite the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary of HHS." *Id.* PPAs must "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1).

Through Section 340B, Congress leverages the federal government's subsidization of healthcare—Medicare and Medicaid cover "almost half the annual nationwide spending on prescription drugs," *Sanofi Aventis*, 58 F.4th at 699 (citing Cong. Budget Off., Prescription Drugs: Spending, Use, and Prices 8 (2022))—to aid covered entities in their mission to care for low-income Americans, *see id.* The statute enables covered entities "to give uninsured patients drugs at little or no cost." *Id.* Covered entities also obtain "extra revenue from serving insured patients" because "they turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount." *Id.* (citing Gov't Accountability Off., Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement 17–18 (GAO-11-836, Sept. 2011)).

As the Supreme Court observed, Congress "intended for the 340B program's drug reimbursements to subsidize other services provided by 340B hospitals" because they "perform valuable services for low-income and rural communities but have to rely on limited federal funding

for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 730, 738 (2022). A federal district court has also discussed how "the purpose of the 340B program was to provide a means to make 340B entities profitable." *Genesis Health Care, Inc. v. Becerra*, Case No. 4:19-CV-01531-RBH, 2023 WL 7549156, at *1 (D.S.C. Nov. 3, 2023).

According to a House Report on Section 340B, Congress enacted Section 340B in response to pharmaceutical manufacturers increasing prices of drugs to make up for lost revenue after Congress enacted the Omnibus Budget Reconciliation Act of 1990, which created the Medicaid Drug Rebate Program. *Id.* (citing H.R. Rep. No. 102-384(II), at 7–11 (1992)). Congress's goal, as stated in House Report 384(II), was to protect covered entities from such price increases because they "reduced the level of services and the number of individuals that these hospitals and clinics" could serve. *Id.* (quoting H.R. Rep. No. 102-384(II), at 11).

Congress's goal was that "the 340B program would 'enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'" *Genesis Health Care*, 2023 WL 7549156, at *1 (quoting H.R. Rep. 102-384(II), at 12) (alteration in original). In other words, Congress wanted to ensure certain healthcare providers can afford to provide the care that qualifies an entity to be a covered entity under 42 U.S.C. § 256b. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996) (hereinafter "August 1996 Guidance") (discussing how covered entities could "use savings realized from participation in the program to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize, and expand services and formularies"). Section 256b(a)'s text plainly shows that purpose by requiring that manufacturers offer covered entities discounts. *See* 42 U.S.C. § 256b(a)(1)–(4).

Section 340B contains two provisions that prohibit covered entities from abusing their ability to obtain discounted drugs. Covered entities cannot "resell or otherwise transfer" discounted drugs "to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). Covered entities also cannot obtain "duplicate discounts or rebates," meaning they cannot obtain Medicaid rebates under Title XIX of the Social Security Act, *see* 42 U.S.C. § 1396, *et seq.*, for drugs that they purchase at a discount under Section 340B, *see* 42 U.S.C. § 256b(a)(5)(A)(i).

To ensure covered entities do not resell discounted drugs or obtain duplicate discounts, the statute contains an auditing provision that states:

> A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

42 U.S.C. § 256b(a)(5)(C). "If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing," that the covered entity illegally resold discounted drugs or obtained duplicate discounts, "the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug . . . provided under the agreement between the entity and the manufacturer." 42 U.S.C. § 256b(a)(5)(D).

To ensure compliance with the 340B diversion and duplicate discount prohibitions, covered entities often require contract pharmacies to use what is commonly known as a "replenishment system" (Dkt. No. 154, at 23–29, 33). Under a replenishment system, the pharmacy dispenses a drug from its own inventory—sometimes referred to as "neutral" inventory—pending review of the covered entity's medical records to determine whether the

individual is a patient of the covered entity and that the individual is not a Medicaid beneficiary (*Id.,* at 24–29). After a determination is made that the individual is eligible to receive 340B drugs, the covered entity purchases a 340B drug on its account to replace, or replenish, the drug that the contract pharmacy dispensed (*Id.,* at 24). That 340B drug is then delivered to the pharmacy to fulfill the replenishment (*Id.*, at 24–25). Covered entities do not sell or transfer 340B drugs to contract pharmacies (*Id.*, at 10, 24–28, 30–32). The covered entity's patient receives the 340B drug, and the covered entity is paying the pharmacy back for a drug that it dispensed from its own inventory (*Id.*, at 24).

Under a variation of this system known as "credit" replenishment, the covered entity makes the same determination of whether an individual qualifies to receive 340B drugs. After the covered entity verifies that the pharmacy dispensed drugs to an individual who is eligible to receive 340B drugs, a second determination is made whether the pharmacy has purchased those same drugs in the recent past. If the pharmacy has purchased the drugs recently, the covered entity's 340B drug order substitutes for the drugs that were previously delivered to the pharmacy.

Whether a covered entity elects to use a physical inventory or replenishment to manage inventory at its contract pharmacy, the covered entity purchases the 340B drug and a delivery of the drug is made to the pharmacy (*Id.*, at 23–29). If a drug company believes 340B drugs are being dispensed to individuals who are ineligible to receive those drugs, the 340B statute entitles it to audit the covered entity and bring an action before a federal administrative dispute resolution panel. 42 U.S.C. § 256b(d)(3).

The issue in this case concerns how discounted drugs under Section 340B are delivered to patients of covered entities. *See* August 1996 Guidance at 43,549 ("The statute is silent as to permissible drug distribution systems."). Section 340B does discuss distribution, directing the

Secretary to "establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs," and providing, "[i]f a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution." 42 U.S.C. § 256b(a)(8). These provisions do not mandate how delivery is to occur, and § 256b(a)(8) does not expressly permit or forbid covered entities to pay for drugs to be delivered or dispensed to patients off their physical premises.

HRSA has attempted to fill the statutory silence about delivery with guidance. Between 1996 and March 2010, HRSA's August 1996 Guidance "acknowledged that section 340B 'is silent as to permissible drug distribution systems,' but it nonetheless sought to fill 'gaps in the legislation' and thereby 'move the program forward.'" *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456–57 (D.C. Cir. 2024) (quoting August 1996 Guidance at 43,549–50). Given that "many covered entities use outside pharmacies to distribute drugs to their patients," HRSA's 1996 Guidance "stated that a covered entity without an in-house pharmacy may contract with a single outside pharmacy to dispense drugs at a single location." *Id.* at 457 (citing August 1996 Guidance at 43,555). The August 1996 Guidance also required that, "in directing shipments to its contract pharmacy," the covered entity "must retain title to the drugs and thus 'be responsible' for any diversion or duplicate discounts." *Id.* (citing August 1996 Guidance at 43,553).

The August 1996 Guidance did not conclude that use of a contract pharmacy, in and of itself, constitutes illegal diversion under § 256b(a)(5)(B). *See* August 1996 Guidance at 43,549–50 ("If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance."); *see also id.* (explaining how, because "[the statute] is silent as to permissible drug distribution systems," and "[t]here is no requirement for a covered

entity to purchase drugs directly from the manufacturer or to dispense drugs itself," "[i]t is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities"). The August 1996 Guidance responded to extensive comments concerning "[p]otential [d]rug [d]iversion." *Id.*, at 43,552. HRSA ultimately concluded that risks of diversion did not warrant precluding covered entities without in-house pharmacies from dispensing 340B drugs that they purchase at a contract pharmacy, and it noted how "[a]lthough some manufacturers expressed concerns regarding the potential for drug diversion, the Department ha[d] received no evidence of diversion that has required an official Departmental investigation." *See id.* at 43,549, 43,552.

HRSA also noted that, while its guidelines would require that "only one site [be] used for" contract pharmacy services, the Office of Drug Pricing ("ODP") would "be evaluating the feasibility of permitting these covered entities to contract with more than one site and contractor." *Id.* at 43,555. The August 1996 Guidance appears to have set forth guidelines in the way of compromise, not an interpretation that the statute's silence about delivery implies a one-pharmacy limit for covered entities without in-house pharmacies. *See id.*, at 43549–50 (referring to its proposal as "guidelines" issued because "there were many gaps in the legislation, and some form of program structure was necessary to move the program forward").

In 2010, HRSA decided that it was no longer appropriate for its guidelines to limit the number of contract pharmacies that covered entities could use. HRSA's 2010 Guidance took the position that "covered entities may contract with an unlimited number of outside pharmacies and may do so regardless of whether the entities have in-house pharmacies." *Novartis*, 102 F.4th at 457 (citing Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010) (hereinafter "2010 Guidance")). In its view, this

Guidance "would permit covered entities to utilize more effectively the 340B program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies and patients." 2010 Guidance at 10,273.

In its 2010 Guidance, HRSA did not change its view that covered entities "must maintain title to and responsibility for the drugs." *Novartis*, 102 F.4th at 457 (citing 2010 Guidance at 10,277). HRSA considered comments following the release of proposed guidelines in 2007, Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 72 Fed. Reg. 1,540 (Jan. 12, 2007) (hereinafter "2007 HRSA Notice"), asserting that allowing covered entities to dispense Section 340B drugs through multiple contract pharmacies would enable diversion and duplicate discounts, see 2010 Guidance at 10,272–75. However, it ultimately decided that covered entities could use multiple contract pharmacies if "they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition," including that "[a]uditable records must be maintained to demonstrate compliance with those requirements." *Id.* at 10,273.

In 2020, concerned with the distribution models in use, many pharmaceutical manufacturers sought to prevent covered entities from using multiple contract pharmacies to dispense Section 340B drugs by implementing policies "limit[ing] the number and kinds of contract pharmacies to which they would ship orders." *Novartis*, 102 F.4th at 458.

As the United States Court of Appeals for the D.C. Circuit recognized, "[m]anufacturers," like AstraZeneca, "have argued that these arrangements lead to unlawful diversion and duplicate discounts." *Id.* Under the replenishment model, "[t]he covered entity [and] the pharmacy . . . often divvy up the spread between the discounted price and the higher insurance reimbursement rate." *Id.* at 457. So, covered entities and contract pharmacies both have "a financial incentive

to catalog as many prescriptions as possible as eligible for the discount." *Id.* at 457–58. Conversely, it seems evident that pharmaceutical manufacturers would prefer as few orders of their products be considered discount eligible as possible.

In 2020, in response to manufacturers' policies limiting distribution to contract pharmacies, HHS issued an advisory opinion stating that pharmaceutical manufacturers were required to permit Section 340B drugs to be delivered to an unlimited number of contract pharmacies. *See Sanofi Aventis*, 58 F.4th at 701 (citing HHS Off. Gen. Couns., Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program (Dec. 30, 2020), https://perma.cc/L7W2-H597 (hereinafter "2020 Advisory Opinion")). "HHS reasoned that 340B drugs are 'purchased by' a covered entity no matter how they are distributed," and so, "the 'situs of delivery . . . is irrelevant.'" *Id.* at 701 (citing 2020 Advisory Opinion at 1–3). Both the United States Court of Appeals for the Third Circuit and the United States Court of Appeals for the D.C. Circuit concluded, however, that Section 340B is silent about delivery and that the federal statute's requirement that manufacturers offer discounts to covered entities did not implicitly permit HHS to mandate that they comply with any delivery practice the covered entities desire. *See id.* at 703–06; *Novartis*, 102 F.4th at 460–63.

In response, states have begun to impose explicitly what HHS had purported to impose by guidance. In 2021, Arkansas enacted Act 1103, which "prohibits pharmaceutical manufacturers from interfering in a covered entity's agreement with a contract pharmacy by denying the pharmacy access to a covered entity's 340B drugs," and "prohibits pharmaceutical manufacturers from interfering in a covered entity's agreement with a contract pharmacy by denying 340B drug pricing to covered entities who use contract pharmacies for distribution." *Pharm. Rsch. &*

Manufacturers of Am. v. McClain, 95 F.4th 1136, 1143 (8th Cir. 2024) (citing Ark. Code Ann. § 23-92-604(c)) (hereinafter "*PhRMA* Case").

An association of pharmaceutical manufacturers sought an injunction against enforcement of the Arkansas law on a theory that Section 340B preempts it. 95 F.4th at 1139–40. This Court and the United States Court of Appeals for the Eighth Circuit disagreed. *Id.* As to field preemption, the Eighth Circuit concluded that "the 340B Program is not so pervasive that Congress left no room for the States to supplement it," given that the statute "'is silent about delivery' of drugs to patients." *Id.* at 1143 (quoting *Sanofi Aventis U.S. LLC*, 58 F.4th at 703). Concerning conflict preemption, because the Arkansas law "does not require manufacturers to provide 340B pricing discounts to contract pharmacies," and "does not set or enforce discount pricing," the Eighth Circuit found that "the delivery of a covered entity's 340B drugs to contract pharmacies for dispensing creates no obstacle" to the statute's purpose. *Id.* at 1145. In fact, the Eighth Circuit observed that the Arkansas law "assists in fulfilling the purpose of 340B," in that it facilitates the distribution and dispensation of discounted 340B drugs. *Id.*

In its motion for summary judgment, AstraZeneca asserts that this case is different because the Court now has both a record of the law's actual application and discovery evidence. In the motion for summary judgment filed by AID and DCMC, AID and DCMC contend that AstraZeneca's claims are barred by claim and issue preclusion because all of AstraZeneca's claims could have been brought in the *PhRMA* Case and because the issue of whether Act 1103 affects drug pricing was settled in the *PhRMA* Case. Additionally, AID and DCMC argue that, even if AstraZeneca's claims are not precluded, those claims fail as a matter of law.

II. Applicable Law

Summary judgment is appropriate if there is no genuine issue of material fact for trial. *UnitedHealth Group Incorporated v. Executive Risk Specialty Ins. Co.*, 870 F.3d 856, 861 (8th Cir. 2017) (citing Fed. R. Civ. P. 56). Summary judgment is proper if the evidence, when viewed in the light most favorable to the nonmoving party, shows that there is no genuine issue of material fact and that the defendant is entitled to entry of judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "In ruling on a motion for summary judgment, '[t]he district court must base its determination regarding the presence or absence of a material issue of factual dispute on evidence that will be admissible at trial.'" *Tuttle v. Lorillard Tobacco Co.*, 377 F.3d 917, 923–24 (8th Cir. 2004) (internal citations omitted). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." *Johnson Reg'l Med. Ctr. v. Halterman*, 867 F.3d 1013, 1016 (8th Cir. 2017) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986)). A factual dispute is genuine if the evidence could cause a reasonable jury to return a verdict for either party. *Miner v. Local 373*, 513 F.3d 854, 860 (8th Cir. 2008). "The mere existence of a factual dispute is insufficient alone to bar summary judgment; rather, the dispute must be outcome determinative under prevailing law." *Holloway v. Pigman*, 884 F.2d 365, 366 (8th Cir. 1989) (citation omitted).

However, parties opposing a summary judgment motion may not rest merely upon the allegations in their pleadings. *Buford v. Tremayne*, 747 F.2d 445, 447 (8th Cir. 1984). The initial burden is on the moving party to demonstrate the absence of a genuine issue of material fact. *Celotex Corp.*, 477 U.S. at 323. The burden then shifts to the nonmoving party to establish that there is a genuine issue to be determined at trial. *Prudential Ins. Co. v. Hinkel*, 121 F.3d 364, 366 (8th Cir. 2008), *cert. denied*, 522 U.S. 1048 (1998). "The evidence of the non-movant is to be

believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) (citation omitted).

III. Discussion

A. Presumption Against Preemption

AstraZeneca argues that the presumption against preemption does not apply in this case because Act 1103 regulates transactions between participants in a federal program and because no historic presence of regulating drug pricing exists (Dkt. No. 132, at 38–40 (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001))). However, a state law regulating health and safety falls within a state's traditional police powers. *See Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 710, 716 (1985) (holding that a local regulation of blood donation centers, including "donor testing and recordkeeping requirements beyond those contained in the federal regulations," was not preempted because the challenger did not "present a showing of implicit pre-emption of the whole field, or of a conflict between a particular local provision and the federal scheme, that [was] strong enough to overcome the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation").

Act 1103 plainly falls under the umbrella of health and safety regulations. It prohibits manufacturers from refusing to deliver Section 340B drugs to contract pharmacies, presumably to maximize covered-entity patients' access to drugs for which the manufacturers have already agreed to provide a discount. Act 1103 triggers the presumption against preemption. *See PhRMA Case*, 95 F.4th at 1144 (holding that Section 340B does not preempt state law prohibiting manufacturers from precluding covered entities from making dispensation contracts with pharmacies in part because "[p]harmacy has traditionally been regulated at the state level, and we

must assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted").

B. Patent Law Preemption

AstraZeneca asserts that Act 1103 is preempted by federal patent law because it regulates drug pricing. It contends that state laws that cap or fix the price at which patented drugs may be sold 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" (Dkt. No. 132, at 22 (citing *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1373–74 (Fed. Cir. 2007))). "In considering preemption of state laws which potentially conflict with federal patent law, courts look to whether a state law 'clashes with the objectives of the federal patent laws.'" *Novartis Pharms. Corp.*, 738 F.Supp.3d 737, 752 (S.D. Miss. 2024) (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974)). AstraZeneca contends that Act 1103, in effect, lowers prices on drugs not already discounted under Section 340B, and, therefore, substantially interferes with the incentives created by patent laws. DCMC argues that Act 1103 does not cap or fix drug prices, only the federal 340B program does.

This Court ruled, and the Eighth Circuit affirmed, that Act 1103 on its face does not require manufacturers to provide 340B pricing discounts to contract pharmacies nor does the law set or enforce discount pricing. *PhRMA Case*, 95 F.4th at 1143. While AstraZeneca acknowledges the Eighth Circuit's ruling in the *PhRMA* Case, it reiterates the facial challenge to Act 1103 made in the *PhRMA* Case, contends the AID Commissioner's enforcement of Act 1103 demonstrates that it regulates pricing, and argues that the use of the "replenishment model" proves that Act 1103 is designed to generate pricing discounts.

In their memorandum in support of their cross-motion for summary judgment and response to AstraZeneca's motion for summary judgment, AID and DCMC renew their position that all of AstraZeneca's claims should be dismissed on issue and claim preclusion grounds (Dkt. No. 149 at 7, 36–47). Alternatively, they contend that nothing in the record shows that Act 1103 requires pharmaceutical manufacturers to offer 340B drugs below applicable ceiling prices, expands the definition of what a 340B healthcare provider is, or expands the remedies available to a covered entity when a manufacturer overcharges it for 340B drugs.

AstraZeneca argues that preemption applies because Act 1103 is a price regulation that "directly conflicts with, and thus is preempted by, the federal patent law." (Dkt. No. 132, at 6). AstraZeneca cites *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) (hereinafter "*Bio*") to support its position (*Id.*). In *Bio*, the District of Columbia city council adopted legislation prohibiting "any patented drug from being sold in the district for an excessive price." *Bio*, at 1364. The Federal Circuit found that one of the objectives of the Patent Clause of the Constitution as well as federal patent statutory protections is to balance the tension between two objectives: "to reward innovators with higher profits and to keep prices reasonable for consumers." *Id.* at 1373. The court held that the District of Columbia price statute expressly targeted the price of patented drugs and thus fell directly "within the scope of the patent laws, and its effect is to shift the benefits of a patented invention from inventors to consumers." *Id.* at 1373–74. Therefore, the District of Columbia statute "re-balance[s] the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Id.* at 1374. The Federal Circuit concluded that the District of Columbia council's efforts conflicted with "the goals established by Congress in the patent laws" because the District of Columbia council's legislation was expressly "targeted at the patent right" and "applies only to patented drugs." *Id.*

Here, unlike the District of Columbia law, Act 1103 does not, on its face or in practice, target patent rights or apply only to patented drugs. As a condition of participating in Medicare and Medicaid, participating pharmaceutical companies agree to provide discounted drugs in the Section 340B program. These discounts are set by the federal government, not the State of Arkansas or Act 1103. Moreover, while *Bio* did set limits on a state's ability to cap the price of patented drugs, "Congress never intended that the patent laws should displace the police powers of the States." *Webber v. State of Virginia*, 103 U.S. 344, 347–48 (1880). Here, a law that neither caps the price of a patented drug nor specifically targets patented drugs cannot justifiably be found preempted under *Bio*. This is particularly true because such a finding would inhibit Arkansas' ability to protect public health, an area long recognized as a traditional police power. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996).

AstraZeneca notes that Act 1130 identifies the drugs it regulates in terms of their price. For example, Act 1130 states that manufacturers shall not:

> [p]rohibit a pharmacy from contracting . . . with an entity authorized to participate in 340B drug pricing . . . or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing.

Ark. Code Ann. § 23-92-604(c). A 340B drug is defined as any drug discounted under the Section 340B program that has been purchased by a covered entity. Act 1103 goes on to define "340B drug pricing" by reference to the 340B program, 42 U.S.C. § 256b(a)(1). AstraZeneca also highlights enforcement proceedings where the AID Commissioner made findings that differentiate AstraZeneca's products based on pricing. In AstraZeneca's view, the fact that these drugs are identified by their price, no matter the context, is enough to make Act 1103 a regulation of price. However, based on the text of the statute and the record in this case, Section 340B sets the price

of the discounted drugs; Act 1103 merely dictates that those drugs must be made available at more locations—namely, at unlimited contract pharmacies.

AstraZeneca further argues that the use of the "replenishment model" shows that Act 1103 regulates price (Dkt. No. 132, at 26–27). Under the replenishment model, discounted and non-discounted drugs are intermingled on the shelves of the pharmacy, and it is not determined by the pharmacy which drugs are discounted under Section 340B until they are already dispensed. *Novartis,* 102 F.4th at 457–58. As a result, AstraZeneca contends that, "[b]ecause the drug is already in the hands of the contract pharmacy before the patient arrives at the pharmacy, the question is not about delivery of the drug" (Dkt. No. 132, at 32) (quoting *PhRMA v. Morrisey*, 760 F. Supp. 3d 439, 455 (S.D.W. Va. 2024)).

However, "[r]eplenishment inventory systems are commonplace [and] . . . pharmaceuticals distribution often relies on pharmaceuticals' fungibility to facilitate efficiency." *AbbVie Inc. v. Fitch*, Case No. 1:24-cv-184-HSO-BWR, 2024 WL 3503965, at *14 (S.D. Miss. July 22, 2024), *aff'd*, Case No. 24-60375, 2025 WL 2630900 (5th Cir. Sept. 12, 2025), and *aff'd*, 152 F.4th 635 (5th Cir. 2025). The Court agrees that the replenishment model is a means of efficient distribution, and AstraZeneca's argument reflects a "technicality," which does not suddenly make Act 1103 a regulation of price. *See id.*, at *15 (stating that the replenishment model facilitates efficient distribution of Section 340B drugs and that reality cannot "be undercut by technicality").

Accordingly, Act 1103 does not regulate price and is not preempted by federal patent law. AstraZeneca's motion for summary judgment on its federal patent law preemption claim is denied (Dkt. No. 131), and AID and DCMC's cross-motion for summary judgment on this claim is granted (Dkt. No. 136).

C. Contract Clause Claim

In Count II, AstraZeneca alleges that Act 1103 violates the Contract Clause of the United States Constitution. Specifically, AstraZeneca contends that it signed a pharmaceutical pricing agreement ("PPA") with the federal government that did not obligate it to offer discounts for unlimited contract pharmacy sales (Dkt. No. 132, at 41–54). In its memorandum in support of its cross-motion for summary judgment, DCMC argues that no evidence supports a violation of the Contract Clause (Dkt. No. 149, at 73–79).

The Contract Clause of the United States Constitution provides that no state shall "pass any law impairing the Obligation of Contracts." U.S. Const. art. I, § 10, cl. 1. A three-part test determines whether state action violates the Contract Clause. First the court asks whether "the state law has, in fact, operated as a substantial impairment on pre-existing contractual relationships." *Am. Fed'n of State, Cnty. & Mun. Emps. v. City of Benton, Arkansas*, 513 F.3d 874, 879 (8th Cir. 2008) (quoting *Equip. Mfrs. Inst. v. Janklow*, 300 F.3d 842, 850 (8th Cir. 2002)). The first prong involves a three-part inquiry: " whether there is a contractual relationship, whether a change in law impairs that contractual relationship, and whether the impairment is substantial." *Gen. Motors Corp v. Romein*, 503 U.S. 181, 186 (1992). If substantial impairment exists, the court will determine whether the state has a "significant and legitimate public purpose behind the regulation." *Educ. Employees Credit Union v. Mut. Guar. Corp.*, 50 F.3d 1432, 1438 (8th Cir. 1995). If there is no significant and legitimate public purpose, the state law is unconstitutional under the Contract Clause. *See Equip. Mfrs.*, 300 F.3d at 850. However, if the state identifies such a public purpose, the court will consider "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." *Energy Reserves Group, Inc. v. Kan. Power & Light Co.*, 459 U.S. 400, 412 (1983) (internal quotation omitted).

AstraZeneca argues that Act 1103 substantially impairs its contractual relationship with the federal government under its PPA. Under the § 340B Program, manufacturers sign PPAs with HHS promising to provide discounted drugs to covered entities as a condition of receiving Medicaid and Medicare Part B reimbursements. According to AstraZeneca, Act 1103 interferes with that agreement by expanding the list of covered entities and imposing costly new obligations on it.

The Court disagrees. Act 1103 does not alter the terms, rights, or obligations of AstraZeneca's PPA with the federal government. Where Act 1103 addresses acquisition and delivery of discounted drugs to contract pharmacies, the PPAs are silent. Nor does Act 1103 undeniably expand AstraZeneca's obligations to provide discounts for unlimited contract pharmacy sales. The D.C. Circuit and Third Circuit, in their decisions on which AstraZeneca relies, held only that HHS lacks authority under Section 340B to mandate delivery to unlimited contract pharmacies. They did not hold—nor suggest—that states lack authority to regulate delivery through their traditional police powers. *See Novartis*, 102 F.4th at 460, 464; *Sanofi*, 58 F.4th at 703.

AstraZeneca's reliance on *Association of Equipment Manufacturers v. Burgum*, 932 F.3d 727 (8th Cir. 2019), is not persuasive. There, the Eighth Circuit affirmed a district court decision to preliminarily enjoin a North Dakota law that prohibited farm equipment manufacturers from imposing certain obligations on dealers, notwithstanding that these obligations were set forth in existing contracts. *Id.*, at 729–30. The Eighth Circuit had "previously held that a similar retroactive law governing agreements between farm equipment dealers and manufacturers in South

Dakota violated the Contract Clause" and that, therefore, the law was unforeseeable, and the manufacturers had no "appreciable warning of an impending intervention into their agreements." *Id.* Here, there is no prior law that would make Act 1103 unforeseeable, and this case involves an industry with an extensive history of state regulation. Additionally, Act 1103 does not rewrite PPAs or impose new contractual terms. AstraZeneca points to nothing in its PPA that addresses—much less limits—delivery to contract pharmacies.

The absence of delivery terms in the PPAs is dispositive. Because delivery logistics were never part of the federal pricing agreements, a covered entity's decision to use a contract pharmacy—and Act 1103's requirement that manufacturers not interfere with that choice—does not alter the contractual bargain between AstraZeneca and the federal government. AstraZeneca entered its PPA as part of a comprehensive federal program governing pharmaceutical pricing—within a heavily regulated industry in which state and federal oversight have long coexisted. That history of regulation put AstraZeneca on notice. And while the PPAs do not expressly contemplate state regulation of delivery to contract pharmacies, that silence cuts against AstraZeneca, not in its favor. Because the agreements say nothing about delivery at all, AstraZeneca could not reasonably expect that delivery obligations would arise exclusively from federal law.

For all of these reasons, Act 1103 does not substantially impair AstraZeneca's contractual obligations under the PPA. AstraZeneca's motion for summary judgment on its Contract Clause claim is denied (Dkt. No. 131). AID and DCMC's cross-motion for summary judgment on this claim is granted (Dkt. No. 136).

D. Takings Clause Claim

AstraZeneca alleges in Count III that Act 1103 violates both the Takings Clause of the United States and Arkansas Constitutions by a physical appropriation of manufacturers' prescription drugs by contract pharmacies and covered entities (Dkt. No. 132, at 54–58).[4] Alternatively, AstraZeneca alleges in Count III that, if not a physical appropriation, it would still constitute a regulatory taking (*Id.*, at 58–60). AID and DCMC argue that Act 1103 neither forcibly takes property from AstraZeneca nor constitutes a regulatory taking (Dkt. No. 149, at 79–88).

The federal Fifth Amendment's Takings Clause, which is applicable to the states under the Fourteenth Amendment, provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const. amend. V. The Takings Clause protects property owners from both physical and regulatory takings—the "direct appropriation of property" by governmental actors and imposition of "restriction[s] on the use of property that went 'too far.'" *Horne v. Dep't of Agric.*, 576 U.S. 350, 360 (2015) (quoting *Penn. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922)). In either event, "[t]he government must pay for what it takes." *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 148 (2021).

1. Physical Appropriation

AstraZeneca contends that Act 1103 requires it to transfer title to and possession of its property—prescription drugs—to other private parties: covered entities and contract pharmacies.

[4] No party has argued that the United States Constitution and Arkansas Constitution differ as to this claim, so as to require a separate analysis under the Arkansas Constitution. Further, as the relevant portions of the United States Constitution and Arkansas Constitution use substantially similar language, the Court sees no reason to treat the claims under the two clauses differently. *Compare* U.S. Const. amend. V ("nor shall private property be taken for public use, without just compensation"), *with* Ark. Const. art. II, § 22 ("private property shall not be taken, appropriated or damaged for public use, without just compensation therefor").

DCMC asserts that Act 1103 does not forcibly take any property from AstraZeneca or compel a transfer of title to contract pharmacies and that, therefore, AstraZeneca's argument for a physical appropriation of private property must fail.

The government effectuates a physical taking when it "physically takes possession of an interest in property for some public purpose." *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 535 U.S. 302, 322 (2002). Examples of physical takings include when the government "uses its power of eminent domain to formally condemn property," "physically takes possession of property without acquiring title to it," or "occupies property"—whether on its own behalf or for the benefit of a third party. *Cedar Point Nursery*, 594 U.S. at 147–48.

AstraZeneca has not submitted evidence that Act 1103 effectuates a physical taking of its property. The record indicates that Act 1103 does not impose on drug manufacturers a positive obligation to transfer directly or sell their drugs to anyone. Nor does the record indicate that Act 1103 requires them to sell larger quantities of their drugs at discounted prices than Section 340B requires and thereby deprive them of sales at full market price. Under Act 1103, AstraZeneca still receives payment of the full discounted amounts to which it is entitled under Section 340B. Act 1103 simply imposes on drug manufacturers a negative obligation of non-interference with covered entities' arrangements with contract pharmacies, by preventing them from refusing to sell Section 340B drugs to covered entities that have arrangements with contract pharmacies.

2. Unconstitutional Regulatory Taking

AstraZeneca contends that Act 1103 has: (1) a profound economic impact on the value of the property subject to the law; (2) significantly interferes with its investment-backed expectations; and (3) forces it to transfer title to its property, depriving it of full use and enjoyment of said property.

The default test for determining whether a regulation constitutes a taking is known as the *Penn Central* Test. The *Penn Central* Court crafted a test that focuses largely "upon the particular circumstances [in each] case." *Becker v. City of Hillsboro, Mo.*, 125 F.4th 844, 852 (8th Cir. 2025) (quoting *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 130-31 (1978)). Under the *Penn Central* balancing test, courts consider: (1) "the economic impact of the regulation on the claimant," (2) "the extent to which the regulation has interfered with distinct investment-backed expectations," and (3) "the character of the government[] action." *Penn Cent. Transp.*, 438 U.S. at 124.

AstraZeneca claims that Act 1103 effects a *per se* taking of its drugs for private use. AstraZeneca claims that Act 1103 does so because it forces pharmaceutical manufacturers subject to Section 340B to sell their products at discounted rates to private pharmacies. AstraZeneca asserts that a taking occurs each time a drug manufacturer is required, against its own volition, to transfer its drugs at the 340B discount price to a commercial pharmacy for the private benefit of that pharmacy (Dkt. No. 132, at 54).

AstraZeneca also maintains that "the voluntary participation doctrine" is inapplicable here (*Id.*, at 60–62). AstraZeneca acknowledges that, "[u]nder certain circumstances, voluntarily accepting a government benefit in exchange for giving up property rights can extinguish a takings claim against the government who conferred the bargained-for benefit" (*Id.*, at 60 (citing *Ruckelshaus v. Monsanto Co.,* 467 U.S. 986, 1007 (1984))). However, AstraZeneca contends its participation in federal Medicare and Medicaid programs—and the assumption of federal obligations under the 340B program—cannot justify the separate state requirements Act 1103 seeks to impose because Arkansas provides no additional benefit to it under Act 1103 (*Id.* (quoting *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023))).

The Court does not agree with AstraZeneca's characterization of Act 1103 as compelling direct, confiscatory sales from pharmaceutical manufacturers subject to Section 340B to private pharmacies. The statute only requires AstraZeneca to offer 340B drugs for purchase by covered entities, regardless of whether the covered entity will have those drugs delivered and dispensed to its patients at a private pharmacy with which it has an arrangement. Because Act 1103 does not compel AstraZeneca to sell directly 340B drugs to pharmacies, Act 1103 does not cause takings for private use according to even AstraZeneca's theory. Nor is the Court persuaded that the manner of delivery to covered-entity patients can constitute a *per se* taking: AstraZeneca is still only required to sell at 340B discounts to covered entities, and AstraZeneca like other pharmaceutical manufacturers can still only have drugs dispensed to their patients.

To the extent that Act 1103's delivery obligation can be considered a regulatory limit on AstraZeneca's property rights, it is not a taking under *Penn Central*. In *Monsanto*, applying *Penn Central* to a voluntary exchange involving the disclosure of trade secrets contained in license applications, the Supreme Court found such disclosure was foreseeable even before Congress amended the Federal Insecticide Fungicide, and Rodenticide Act ("FIFRA") to warn explicitly of disclosure. 467 U.S. at 1008. That states might require Section 340B drugs to be distributed for dispensation at private pharmacies should have been foreseeable to AstraZeneca, as Section 340B has had a well-known "gap" about how delivery must occur since Congress enacted it. *See* August 1996 Guidance at 43,549–50 (discussing "gaps" in Section 340B including that it "is silent as to permissible drug distribution systems"). Congress's silence left delivery options open because "a matter not covered is not covered." Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 93 (2012).

Further, when Congress enacted Section 340B, "only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500)," such that the potential for contract pharmacy dispensation was foreseeable. August 1996 Guidance, at 43,550. While the August 1996 Guidance's "guideline[ ]" of one contract pharmacy for covered entities without in-house pharmacies is not consistent with Act 1103, that same Guidance appears to contemplate that state law might protect covered entities' "right" to purchase drugs at 340B prices and have them dispensed at multiple pharmacies. *See id.* (Comment: "As a matter of State [agency] law, [covered] entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients . . . . Response: We agree.").

In "an industry," such as pharmaceuticals, "that long has been the focus of great public concern and significant government regulation," enhanced regulation where Congress was previously silent is foreseeable, which cuts against finding a regulatory taking. *Monsanto*, 467 U.S. at 1008–09. Likewise, because Section 340B does not preempt state laws requiring delivery of 340B drugs to contract pharmacies, AstraZeneca could have foreseen that states might enact policies favoring dispensation at contract pharmacies as well. *See Pace Res., Inc. v. Shrewsbury Twp.*, 808 F.2d 1023, 1033 (3d Cir. 1987) ("[I]nvestment-backed expectations are reasonable only if they take into account the power of the state to regulate in the public interest.").

Further, Act 1103 is "rationally related to a legitimate Government interest." *Monsanto*, 467 U.S. at 1007. The Arkansas Legislature has evidently determined that dispensation of 340B drugs at contract pharmacies advances public health, which falls squarely within its police powers.

To the extent that dispensation of 340B drugs at contract pharmacies will increase the number of medications for which AstraZeneca must provide discounts, and thus cut into its profits, "the economic impact of the regulation" is not drastic, *Cedar Point Nursery*, 594 U.S. at 148, and

will not deprive AstraZeneca of all economically beneficial use of its products, *Lucas*, 505 U.S. at 1019–20.

Based on the record, AstraZeneca's Takings Clause claims fail as a matter of law. AstraZeneca's motion for summary judgment on its Takings Clause claims is denied (Dkt. No. 131), and AID and DCMC's cross-motion for summary judgment is granted.

E. DCMC's Motion To Compel Discovery

On March 20, 2025, DCMC filed its motion to compel discovery (Dkt. No. 91). AstraZeneca filed several unopposed motions to extend time for a response and indicated that the parties were working through their issues (Dkt. Nos. 99; 105; 111; 115; 121; 124). In its response to the motion to compel, AstraZeneca contended that "the parties have resolved the discovery issues raised in the Intervenor's Motion to Compel, rendering the Motion moot" (Dkt. No. 135, at 1). DCMC did not file a reply or otherwise object to this representation made by AstraZeneca. Accordingly, the Court denies as moot DCMC's motion to compel discovery (Dkt. No. 91).

IV. Conclusion

For the foregoing reasons, the Court:

(1) denies as moot DCMC's motion to compel discovery (Dkt. No. 91);

(2) denies AstraZeneca's motion for summary judgment (Dkt. No. 131); and

(3) grants AID and DCMC's cross-motion for summary judgment (Dkt. No. 136).

It is so ordered this 29th day of September, 2026.

Kristine G. Baker
Chief United States District Judge