IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI CENTRAL DIVISION

ASTRAZENCA PHARMACEUTICALS LP,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Case No. 2:24-cv-04143-MDH**
	)	
CATHERINE HANAWAY, in her official capacity as the Attorney General of MISSOURI et al.,	)	
	)	
Defendants,	)	
	)	
MISSOURI HOSPTIAL ASSOCIATION and MISSOURI PRIMARY CARE ASSOCIATION,	)	
	)	
Intervenors.	)	

ORDER

Before the Court are Plaintiff's, Defendants' and Intervenors' cross-motions for summary judgment. (Docs. 193, 197, 198). All parties have filed suggestions in opposition (Docs. 214, 217, 222) and replies (Docs. 229, 235, 237). Nonparties American Hospital Association, 340B Health, and American Society of Health-System Pharmacists have filed an amicus brief in support of Defendants' motion for summary judgment. (Doc. 211). The matter is now ripe for review.

Plaintiff AstraZeneca brought this suit alleging that SB 751 is preempted by federal patent and drug exclusivity laws, preempted by the federal 340B statutory scheme, violates the Contracts Clause, and violates the Takings Clause. This Court dismissed AstraZeneca's preemption and Takings Clause claims but declined to dismiss AstraZeneca's Contracts Clause claim, finding that "Plaintiff ha[d] sufficiently alleged the existence of a contract, that would be substantially impaired by S.B. 751." (Doc. 90, at 7–8). AstraZeneca seeks declaratory and injunctive relief.

BACKGROUND

The background of the 340B Program is by this point well-trodden, the Program having become the subject of frequent litigation in districts in the Eighth Circuit as well as around the country. Section 340B of the Public Health Service Act requires pharmaceutical drug manufacturers participating in federal drug reimbursement markets to offer covered outpatient drugs ("340B drugs") to certain health care providers ("covered entities") at a discounted price.

When Section 340B was enacted, less than five percent of covered entities had in-house pharmacies able to distribute medication to patients. In 1996, the Health Resources and Services Administration ("HRSA") issued guidance allowing covered entities without an in-house pharmacy to partner with a single contract pharmacy. In 2010, HRSA issued updated guidance allowing covered entities to distribute 340B drugs through an unlimited number of contract pharmacies. As a result, the number of contract pharmacies grew rapidly.

In 2020, drug manufacturers began to restrict covered entities' use of contract pharmacies. The Department of Health and Human Services ("HHS") responded by issuing an advisory opinion requiring manufacturers to deliver to unlimited contract pharmacies; drug manufacturers, in turn, sued to enjoin the advisory opinion. The Third Circuit sided with the drug manufacturers, holding that no language in Section 340B *requires* manufacturers to recognize an unlimited number of contract pharmacies and therefore federal agencies lacked the authority to create such a requirement. *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 704 (3d Cir. 2023). The D.C. Circuit likewise held that Section 340B "preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024).

Many states then sought to regulate in the way the Third and D.C. Circuits held the federal government lacked the authority to: preventing pharmaceutical manufacturers from interfering with outside pharmacy arrangements. Missouri's SB 751 is one example:

> A pharmaceutical manufacturer, third-party logistics provider, or an agent or affiliate of such pharmaceutical manufacturer or third-party logistics provider, shall not deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by, a covered entity to receive 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.

Mo. S.B. 751 (102nd Gen. Assemb. 2024) (codified at Mo. Rev. Stat. § 376.414.2). SB 751 requires drug manufacturers participating in the 340B Program to deliver 340B drugs to all of a Missouri covered entity's contract pharmacies. This conflicts with AstraZeneca's current policy limiting delivery of 340B drugs to either a covered entity's in-house pharmacy or a single contract pharmacy designated by the covered entity.

A drug manufacturer participates in the 340B Program by entering into a Pharmaceutical Pricing Agreement ("PPA") with the Department of Health and Human Services ("HHS") that sets out both parties' statutory obligations under the program—the terms of the PPA are the same as the federal law. Those terms include that manufacturers must "offer each covered entity outpatient drugs for purchase" at prices that are discounted under a statutory formula—sometimes for as little as a penny per sale." 42 U.S.C. § 256b(a)(1). Covered entities are not required to pass the discounts on to patients. Many covered entities use the excess revenues from the 340B Program to finance their operations and expand services.

The text of SB 751 was developed by the Missouri Hospital Association ("MHA") and Missouri Primary Care Association ("MPCA"). The two organizations discussed the language they would provide to legislators and were actively involved in the drafting process. The contract-

pharmacy language that eventually became SB 751 would generate revenue for MPCA and MHA's members at the expense of pharmaceutical manufacturers.

STANDARD

A Court will grant summary judgment where, "viewing the record in the light most favorable to the nonmoving party, there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law." *Woods v. DaimlerChrysler Corp.*, 409 F.3d 984, 990 (8th Cir. 2005); *see also* Fed. R. Civ. P. 56. Initially, the moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the movant meets the initial step, the burden shifts to the nonmoving party to "set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). To satisfy this burden, the nonmoving party must "do more than simply show there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986).

DISCUSSION

The Contracts Clause "restricts the power of States to disrupt contractual arrangements," *Sveen v. Melin*, 584 U.S. 811, 818 (2018), and provides that "[n]o State shall … pass any … Law impairing the Obligation of Contracts." U.S. Const. art. I, § 10, cl. 1. Under the clause's modern interpretation, "states have some leeway to alter parties' contractual relationships to safeguard the vital interests of [their] people," and "[i]ndeed, parties contract with an expectation of possible regulation—especially … in highly regulated industries." *AbbVie, Inc. v. Murrill*, 180 F.4th 747, 764 (5th Cir. 2026) (cleaned up and citations omitted).

The first step of analysis is to determine whether the state law has substantially impaired the contractual relationship at issue. The Court considers "the extent to which the law undermines

the contractual bargain, interferes with a party's reasonable expectations, and prevents the party from safeguarding or reinstating his rights." *Sveen*, 584 U.S. at 819.

"Minimal alteration of contractual obligations may end the inquiry at the first stage." *Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234, 245 (1978). However, if substantial impairment is established, the Court then asks whether the challenged law "is drawn in an 'appropriate' and 'reasonable' way to advance 'a significant and legitimate public purpose." *Sveen*, 584 U.S. at 819 (quoting *Energy Rsrvs. Grp., Inc. v. Kan. Power & Light Co.*, 459 U.S. 400, 411–412 (1983)). "Severe impairment … will push the inquiry to a careful examination of the nature and purpose of the state legislation." *Allied Structural Steel*, 438 U.S. at 245.

1. Substantial impairment.

SB 751 forbids AstraZeneca from limiting the delivery of 340B discount drugs to contract pharmacies. The parties dispute whether this amounts even to an "impairment" of AstraZeneca's PPA, let alone a substantial one, for AstraZeneca's PPA itself contains no terms about the delivery of 340B drugs. Although largely an academic distinction for the purposes of this case, the Court agrees with AstraZeneca that SB 751 adds obligations to its PPA. The entire point, after all, of laws like SB 751 is to affect what pharmaceutical manufacturers can and cannot do pursuant to the 340B program. However, it does not follow that SB 751's added obligations amount to substantial impairment. The Court finds that the impairment caused by SB 751 is one that does not undermine AstraZeneca's contractual bargain, upset its reasonable expectations, or impede its rights. *Sveen*, 584 U.S. at 819.

To start, the Eighth Circuit has explained that contracting parties are generally on notice of future state regulation when the parties make a contract in a highly regulated industry. *See Koster v. City of Davenport, Iowa*, 183 F.3d 762, 767 (8th Cir. 1999) ("Generally, the more heavily

regulated the industry, the less reasonable it is to expect that contractual relationships will not be altered by legislation."); *see also Energy Rsrvs. Grp.*, 459 U.S. at 411 ("One whose rights, such as they are, are subject to state restriction, cannot remove them from the power of the State by making a contract about them.") (quotation omitted). And it is well established that regulation of pharmacy is part of a state's police power. *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021).

AstraZeneca contends that the inquiry should be narrower: the subset of regulation regarding *pricing or delivery of 340B drugs* had never previously been regulated by states; thus, for SB 751 to have been foreseeable, it is not enough that states regulate the pharmaceutical industry generally. The Eighth Circuit, in other contexts, has found Contracts Clause violations even in heavily regulated industries. *See e.g., In re Workers' Comp. Refund*, 46 F.3d 813, 820 (8th Cir. 1995) (insurance industry); *Heights Apartments, LLC v. Walz*, 30 F.4th 720, 730 (8th Cir. 2022) (housing industry).

The record does not support that distinction. Although contract pharmacies did not exist under the 340B Program when AstraZeneca first signed its PPA in 1993, they have coexisted with the program since 1996. The history of covered entities contracting first with a single and then with unlimited outside pharmacies over the past twenty years suggests that state regulation over such contracting was foreseeable. *See Murrill*, 180 F.4th at 766 ("AstraZeneca entered into 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."); *Heights Apartments*, 30 F.4th at 729 ("[A]n aggrieved party cannot claim that its expectations were disappointed if it was reasonably foreseeable … that the government could substantially interfere with its contract.").

Moreover, this is not the sort of legislation which fundamentally upends pharmaceutical manufacturers' contractual bargains. AstraZeneca cites to cases where state laws—often in historically unregulated industries—dramatically altered the contracting parties' obligations. *See, e.g., Allied Structural Steel*, 438 U.S. at 246–47 (finding substantial impairment where state law caused a "severe disruption of contractual expectations" that "impose[d] a completely unexpected liability in potentially disabling amounts."). That is far from the outlook here, where SB 751 does not conflict with a single term of AstraZeneca's PPA.

In *AbbVie, Inc. v. Murrill*, the Fifth Circuit concluded that Louisiana's materially similar version of SB 751 did not substantially impair AstraZeneca's PPA: "Act 358 [Louisiana's version of SB 751] does not alter the terms, rights, or obligations of AstraZeneca's PPA with the federal government. … Where Act 358 addresses acquisition and delivery of discounted drugs to contract pharmacies, the PPAs are silent." 180 F.4th at 765. This Court now joins in endorsing a premise underlying *Murrill*: state laws like SB 751 do not substantially impair PPAs, for such laws do not affect pharmaceutical manufacturers' obligations in ways other than reducing those manufacturers' profits. Reduction in profits is not alone appropriate proof for substantial impairment of a contract; that is often the effect of state laws in regulated industries.

2. Public purpose.

Even if a state law substantially impairs a contract, it does not violate the Contracts Clause if it "is drawn in an 'appropriate' and 'reasonable' way to advance 'a significant and legitimate public purpose." *Sveen*, 584 U.S. at 819 (quoting *Energy Rsrvs. Grp.*, 459 U.S. at 411–412).

AstraZeneca contends that SB 751 does not appropriately advance a legitimate public purpose because it operates *only* to "directly alter the obligations and expectations of the contracting parties." *Equip. Mfrs. Inst. v. Janklow*, 300 F.3d 842, 861 (8th Cir. 2002); *see also*

Ass'n of Equip. Mfrs. v. Burgum, 932 F.3d 727, 733 (8th Cir. 2019) ("[T]he Contract Clause demands more than incidental public benefits."). According to AstraZeneca, a law that is primarily intended to benefit covered entities and pharmacies—instead of patients—provides "a benefit to special interests" rather than a "broad and general" benefit as required to serve a "legitimate public purpose." *Energy Rsrvs. Grp.*, 459 U.S. at 411–12.

The Supreme Court has held, concerning the question of "a significant and legitimate public purpose," that "unless the State is itself a contracting party, courts should 'properly defer to legislative judgment as to the necessity and reasonableness of a particular measure.'" *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 505 (1987) (quoting *Energy Rsrvs. Grp.*, 549 U.S. at 413). In *Novartis Pharms. Corp. v. Bailey*, this Court recognized that "[t]he legislature, by virtue of a democratic process, has created a law [SB 751] to protect the delivery of 340B drugs." No. 2:24-cv-04131-MDH, 2025 WL 595189, at *6 (W.D. Mo. Feb. 24, 2025). Against this presumption of deference, AstraZeneca must do more than note that covered entities and contract pharmacies may be the main entities whose interests benefit from SB 751 while AstraZeneca's interests suffer.[1]

As the State and Intervenors note, even if covered entities and contract pharmacies—rather than patients—are primarily the entities that benefit from SB 751, the law still serves a legitimate public purpose. SB 751's savings for covered entities and contract pharmacies allow those entities to provide better overall service to patients. Moreover, "Missouri is a very rural state … And so

[1] AstraZeneca contends that deference to the Missouri legislature would be inappropriate here because the State of Missouri itself runs certain covered entities, such as certain community hospitals. But courts may defer to legislative judgment "*unless the State is a contracting party*." *DeBenedictis*, 480 U.S. at 505 (emphasis added). Moreover, SB 751 not only benefits certain state-run entities but also private covered entities and pharmacies. This is not a situation where the State "welches on its obligations as a matter of political expediency[.]" *Buffalo Teachers Fed'n v. Tobe*, 464 F.3d 362, 370 (2d Cir. 2006) (internal quotations omitted).

having just one contract pharmacy for an FQHC [federally qualified health center], especially[] in rural areas, makes it harder for patients to access their 340B drugs." (Doc. 200-8, at 28:6–12).

"The severity of the impairment measures the height of the hurdle the state legislation must clear." *Allied Structural Steel*, 438 U.S. at 245. Even were the Court to find substantial impairment, what AstraZeneca asks of this Court—to upend the design of the Missouri legislature—is not supported by the record. Where the impairment caused by SB 751 is a reduction in AstraZeneca's revenue due to a regulation not contravening any of the PPA's express conditions, SB 751's avowed purpose is sufficiently public. Even were SB 751 to provide no direct savings to patients (an assumption not established by the record) the Missouri legislature has a prerogative, under its police power, of supporting local health providers.

CONCLUSION

Viewing the record in the light most favorable to Plaintiff, the Court finds no material dispute of fact that SB 751 neither substantially impairs AstraZeneca's contract nor lacks a significant and legitimate public purpose. For the aforementioned reasons, it is **ORDERED** that Plaintiff's motion for summary judgment is **DENIED**, and the Defendants' and Intervenors' motions for summary judgment are **GRANTED**. Summary judgment is hereby entered in favor of Defendants and Intervenors.

IT IS SO ORDERED.

DATED: November 19, 2026

/s/ Douglas Harpool
DOUGLAS HARPOOL
UNITED STATES DISTRICT JUDGE