IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

ASTRAZENECA PHARMACEUTICALS LP — **PLAINTIFF**

v. — **CAUSE NO. 1:24CV196-LG-BWR**

LYNN FITCH in her official capacity as the Attorney General of Mississippi — **DEFENDANT**

MEMORANDUM OPINION AND ORDER DENYING ASTRAZENECA'S MOTION FOR PRELIMINARY INJUNCTION

Plaintiff AstraZeneca Pharmaceuticals LP sued Mississippi Attorney General Lynn Fitch, claiming that Mississippi's "Defending Affordable Prescription Drug Costs Act," Miss. Code Ann. § 41-149-1 et seq., is preempted by the United States' 340B drug program, the Takings Clauses of the Mississippi and United States Constitutions, the Contracts Clause of the United States Constitution, and federal patent law. AstraZeneca now seeks a preliminary injunction as to some of its claims. Since AstraZeneca has failed to demonstrate a substantial likelihood of success on the merits, the Court finds that its [13] Motion should be denied.

BACKGROUND

Section 340B of the Public Health Service Act requires pharmaceutical companies who wish to participate in Medicaid and Medicare Part B to offer discounts on certain outpatient drugs to covered entities, such as public hospitals and community health centers. 42 U.S.C. § 256b(a)(1). The program helps these covered entities provide "safety-net services to the poor" because the entities "turn a

profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113 (2011); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023). The program is administered by the Secretary of Health and Human Services ("HHS") and "superintended by the Health Resources and Services Administration" ("HRSA"), which is an HHS agency. *Id.* at 113; 42 U.S.C. § 256b.

"Drug manufacturers opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement (PPA) used nationwide." *Id.* PPAs are "uniform agreements" that require manufacturers to offer covered entities outpatient drugs at or below a specified price 'if the drug is made available to any other purchaser at any price.'" *Id.*; 42 U.S.C. § 256b(a). "Covered entities may only prescribe 340B discounted drugs to patients who qualify and may not request or receive duplicative 340B discounts and Medicaid rebates for the same drug." *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1141–42 (8th Cir. 2024) (citing 42 U.S.C. § 256b(a)(5)(A)–(B)). Additionally, covered entities may not engage in diversion of 340B drugs through "resell[ing] or otherwise transfer[ring] the drug to a person who is not a patient of the entity." *Id.* (citing 52 U.S.C. § 256b(a)(5)(B)). HHS and drug manufacturers are authorized to audit covered entities to ensure compliance with the diversion and duplicate rebate provisions. *Id.* (citing 52 U.S.C. § 256b(a)(5)(C)). The program contains enforcement mechanisms and penalties for manufacturers and covered entities that fail to comply. *Id.* (citing *Sanofi Aventis*, 58 F.4th at 700).

All disputes arising under the 340B program must first be submitted to HHS's dispute resolution program. *Id.* (citing 42 U.S.C. § 256b(d)(3)).

"Since the beginning, covered entities have contracted with outside pharmacies, referred to as 'contract pharmacies,' for the distribution and dispensation of 340B drugs." *Id.* at 1139. "Indeed, early in the 340B Program, HRSA observed that most covered entities relied on contract pharmacies, while only about four percent of such entities used in-house pharmacies." *Id.* at 1142 (citing Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) ("1996 Guidance")).

In the 1996 Guidance, HHS permitted each covered entity that did not maintain an in-house pharmacy to contract with only one outside pharmacy. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456–57 (D.C. Cir. 2024) (citing 1996 Guidance at 43,555). In 2010, HRSA determined that covered entities should be permitted to contract "with an unlimited number of outside pharmacies and may do so regardless of whether the entities have in-house pharmacies." *Id.* (citing Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010) ("2010 Guidance"). The 2010 Guidance prompted a significant expansion in the use of contract pharmacies. *Id.*

In 2020, out of concern that the use of contract pharmacies resulted in duplicate discounts and diversion, manufacturers began adopting policies that limited or prohibited covered entities from contracting with outside pharmacies for the dispensation of 340B drugs to patients. *McClain*, 95 F.4th at 1139; *Sanofi*

Aventis U.S. LLC, 58 F.4th at 700. "This caused covered entities dependent on contract pharmacies to become unable to serve patients in need." *McClain*, 95 F.4th at 1139.

In response to the manufacturers' new policies prohibiting or restricting contracts with outside pharmacies, HHS released an Advisory Opinion declaring that Section 340B unambiguously requires drug makers to deliver 340B drugs to an unlimited number of contract pharmacies." *Sanofi Aventis*, 58 F.4th at 701 (citing HHS Off. Gen. Couns., *Advisory Op. 20-06 on Cont. Pharmacies Under the 340B Program* (Dec. 30, 2020), https://perma.cc /L7W2-H597)). It also issued violation letters to the manufacturers, who sued HHS. *Id.* The Third Circuit held that the Advisory Opinion and violation letters were unlawful because Section 340B is silent regarding delivery to contract pharmacies. *Id.* at 706. Thus, the court enjoined HHS's "reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies" because "[l]egal duties do not spring from silence." *Id.* at 707. The D.C. Circuit reached the same conclusion. *See Johnson*, 102 F.4th at 459.

In April 2024, in an effort to prevent manufacturers and others "from engaging in certain discriminatory actions relating to entities that are participating or authorized to participate in the federal 340b drug discount program,"[1] the Mississippi Legislature enacted Miss. H.B. 728, which is codified as Miss. Code

[1] H.B. 728, 2024 Leg., 139th Sess. (Miss. 2024).

Ann. § 41-149-1 et seq.[2] H.B. 728 provides:

> (1) A manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, 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 a 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.
>
> (2) A manufacturer or distributor shall not interfere with a pharmacy contracted with a 340B entity.

Miss. Code Ann. § 41-149-7. A violation of this statute constitutes a violation of the Mississippi Consumer Protection Act, which provides for both civil and criminal penalties. Miss. Code Ann. §41-149-9 (citing Miss. Code Ann. § 75-24-1, et seq.).

Drug manufacturer AstraZeneca filed this lawsuit, claiming that H.B. 728 is preempted because it inappropriately expands the federal 340B program by requiring discounts "to an entirely new category of transactions." Compl. [1] at ¶5. It further asserts that the Mississippi statute is preempted by federal patent law. AstraZeneca also alleges that H.B. 728 violates the Contracts Clause of the United States Constitution and the Takings Clause of both the United States Constitution and the Mississippi Constitution.

AstraZeneca is particularly concerned with the manner in which contract pharmacies distribute 340B drugs on behalf of covered entities. It cites the D.C. Circuit's discussion of this process, which is often called "the replenishment model":

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[2] In the interest of clarity and consistency, the Court will refer to the Mississippi statute as "H.B. 728," just as the parties have done in their submissions to the Court.

> 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.

Pl.'s Mem. [14] at 5 (quoting *Johnson*, 102 F.4th at 457–58). AstraZeneca argues that "[t]his means that a 340B discount is applied for the contract pharmacy sale even though the pharmacy has also benefitted from the full insurance reimbursement, resulting in a windfall—a result Congress never intended when it passed the 340B program with the goal of aiding vulnerable patients." *Id.*

In the present Motion, AstraZeneca seeks a preliminary injunction as to its preemption claims. The Court previously addressed most of the arguments asserted by AstraZeneca in the following opinions, which are incorporated herein by reference: *Novartis Pharms. Corp. v. Fitch*, No. 1:24-CV-164-HSO-BWR, 2024 WL 3276407 (S.D. Miss. July 1, 2024); *Pharm. Rsch. & Mfrs. of Am. v. Fitch*, No. 1:24-CV-160-HSO-BWR, 2024 WL 3277365 (S.D. Miss. July 1, 2024); and *AbbVie Inc. v. Fitch*, No. 1:24-CV-184-HSO-BWR, 2024 WL 3503965 (S.D. Miss. July 22, 2024).

DISCUSSION

Fed. R. Civ. P. 65 authorizes entry of a preliminary injunction after notice to the adverse party; nevertheless, this relief is considered an "extraordinary remedy." *Tex. Med. Providers Performing Abortion Servs. v. Lakey*, 667 F.3d 570, 574 (5th Cir. 2012). Thus, the movant must "clearly [carry] the burden of persuasion" on all four of the following requirements:

> (1) a substantial likelihood that they will prevail on the merits, (2) a substantial threat that they will suffer irreparable injury if the injunction is not granted, (3) their substantial injury outweighs the threatened harm to the party whom they seek to enjoin, and (4) granting the preliminary injunction will not disserve the public interest.

Id. (brackets and citations omitted).

I. WHETHER ASTRAZENECA HAS SHOWN A SUBSTANTIAL LIKELIHOOD THAT IT WILL PREVAIL ON THE MERITS

Under the United States Constitution, "both the National and State Governments have elements of sovereignty the other is bound to respect." *City of El Cenizo v. Texas,* 890 F.3d 164, 176 (5th Cir. 2018) (quoting *Arizona v. United States*, 567 U.S. 387, 398 (2012)). However, the Constitution's Supremacy Clause provides that federal legislation "shall be the supreme Law of the Land." *Id.* (quoting U.S. Const. art. VI, cl. 2). Thus, state law is preempted when: "(1) a federal statute expressly preempts state law ('express preemption'); (2) federal legislation pervasively occupies a regulatory field ('field preemption'); or (3) a federal statute conflicts with state law ('conflict preemption')." *Deanda v. Becerra*, 96 F.4th 750,

760–61 (5th Cir. 2024). The first consideration in preemption analysis is whether a presumption against preemption applies. *Id.* at 761.

A. WHETHER A PRESUMPTION AGAINST PREEMPTION APPLIES

A presumption against preemption applies in areas of law traditionally reserved to the states, including "state or local regulation of matters of health and safety." *Id.*; *Pennington v. Vistron Corp.*, 876 F.2d 414, 417 (5th Cir. 1989). This Court has previously determined that H.B. 728 "plainly falls under the umbrella of a health and safety regulation." *See, e.g., AbbVie*, 2024 WL 3503965, at *9. Therefore, AstraZeneca's arguments to the contrary are not well taken, and the presumption against preemption applies.

B. WHETHER CONFLICT PREEMPTION APPLIES

AstraZeneca argues that H.B. 728 is preempted because it conflicts with both the 340B statute and federal patent law. The form of conflict preemption cited by AstraZeneca is called "obstacle preemption" because it applies when a state statute "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *See Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 377 (2015) (quoting *California v. ARC Amer. Corp.*, 490 U.S. 93, 100, 101 (1989)). The question of "[w]hat is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Villas at Parkside Partners v. City of Farmers Branch*, 726 F.3d 524, 528 (5th Cir. 2013) (quoting *Arizona*, 567 U.S. at 400). This Court has previously conducted this analysis, explaining in part:

> 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).

AbbVie, 2024 WL 3503965, at *2.

1. WHETHER H.B. 728 IS AN OBSTACLE TO THE PURPOSES AND OBJECTIVES OF THE FEDERAL 340B PROGRAM

AstraZeneca argues that H.B. 728 "upend[s] Congress's careful structuring of the 340B program" by "dramatically increasing the scope of manufacturers' obligations under the federal program." Pl.'s Reply [30] at 6. AstraZeneca claims that H.B. 728 widens the scope of the 340B program because it reduces the price of additional drugs. Attorney General Fitch counters that H.B. 728 does not alter drug prices but pertains to delivery of drugs to patients—a topic that is not addressed in the 340B statute.

Contrary to AstraZeneca's assertions, H.B. 728 does not alter the prices of covered drugs, which are established by the following provision of the federal 340B program:

> The Secretary [of HHS] shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2).

42 U.S.C. § 256b(a)(1). Furthermore, H.B. 728 does not change the drugs covered by the 340B program. *See* 42 U.S.C. § 256b(b)(2) (defining the term "covered drug"). Rather, H.B. 728 incorporates the 340B pricing formula and the drugs to which it applies by reference. *See* Miss. Code Ann. § 41-149-3(a) ("'340B drug' means a drug that has been subject to any offer for reduced prices by a manufacturer *pursuant to* [42 U.S.C. § 256b] and is purchased by a covered entity *as defined in* [42 U.S.C. § 256b(a)(4)]") (emphasis added).

H.B. 728 merely prohibits drug manufacturers and distributors from interfering with "the acquisition of a 340B drug" by a contract pharmacy or the "delivery of a 340B drug to" such a pharmacy. Miss. Code Ann. § 41-149-7. The Third, Eighth, and D.C. Circuits have held that the 340B program does not address drug delivery. *See McClain*, 95 F.4th at 1142 (holding that a similar Arkansas statute was not subject to obstacle preemption); *see also Sanofi Aventis U.S. LLC*, 58 F.4th at 703 (holding that the 340B program is "silent about delivery"); *Johnson*, 102 F.4th at 456–57 (explaining that "section 340B merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount" and is "silent about delivery conditions"). Since H.B. 728 addresses delivery and 340B does not, AstraZeneca has not demonstrated a conflict between H.B. 728 and HB 340. Furthermore, AstraZeneca has not explained how H.B. 728's provisions concerning delivery of 340B drugs to patients of covered entities obstruct the objectives and purposes of the 340B program.

AstraZeneca next argues that H.B. 728 "establishes a parallel enforcement regime that encroaches on the federal government's authority to set and define federal enforcement priorities." Pl.'s Mem. [14] at 13. Once again, H.B. 728's penalties pertain to delivery, which is not addressed by 340B's enforcement method. As a result, H.B. 728's penalties do not conflict with or obstruct 340B's penalties. *See McClain*, 95 F.4th at 1145. AstraZeneca has not demonstrated a substantial likelihood of success on the merits of its obstacle preemption claim.

2. WHETHER H.B. 728 IS AN OBSTACLE TO THE PURPOSES AND OBJECTIVES OF FEDERAL PATENT LAW

AstraZeneca asserts that H.B. 728 is preempted by federal patent law because it regulates drug pricing. It explains:

> 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."

Pl.'s Mem. [14] at 15 (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.*, 2024 WL 3276407, at *10 (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974)). As explained previously, "H.B. 728 does not purport to lower prices on any drugs not already discounted under Section 340B." *Id.* Therefore, "it does not substantially interfere

with the incentives created by patent laws or other federal laws establishing regulatory exclusivities." *Id.* AstraZeneca has not shown a substantial likelihood of success on the merits of its claim that H.B. 728 is preempted by federal patent law.

C. WHETHER FIELD PREEMPTION APPLIES

Field preemption occurs when "[s]tates are precluded from regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance." *United States v. Texas*, 97 F.4th 268, 278 (5th Cir. 2024).

> The intent to displace state law altogether can be inferred from a framework of regulation "so pervasive . . . that Congress left no room for the States to supplement it" or where there is a "federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject."

Arizona, 567 U.S. at 399 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

The Eighth Circuit and this Court have previously held that Congress did not intend to preempt the field when it enacted 340B. *McClain*, 95 F.4th at 1144; s*ee also, e.g., Pharm. Rsch.*, 2024 WL 3277365, at *12. Both courts reasoned that matters of health and safety are traditionally left to the states. The Fifth Circuit has ruled that courts should not infer field preemption in matters reserved to the states, *Nat'l Press Photographers Ass'n v. McCraw*, 90 F.4th 770, 796 (5th Cir. 2024). Thus, the Court once again finds that field preemption does not apply to H.B. 728. AstraZeneca has not shown a substantial likelihood of success on the merits as to its field preemption claim.

D. SUPPLEMENTAL EVIDENCE SUBMITTED BY ASTRAZENECA

After briefing of AstraZeneca's request for a preliminary injunction concluded, it filed a [31] "Notice of Supplemental Authority" along with a [31-1] 340B Contract Pharmacy Services Agreement between Walgreen Co.[3] and an Arizona covered entity named Neighborhood Outreach Access to Health.[4] The heavily redacted Agreement was signed by its parties in April 2016.

AstraZeneca asserts that Section 3.3.5 and Section 8.10 of the Agreement support its arguments and undermine the Eighth Circuit's decision in *McClain* and this Court's prior decisions in *PhRMA*, *AbbVie*, and *Novartis*. Specifically, AstraZeneca argues that these provisions "confirm that H.B. 728 forces AstraZeneca to offer 340B discounts, and to transfer title to its drugs, to a private company that does not qualify as a covered entity under the 340B statute." Pl.'s Notice [31] at 2.

The first provision cited by AstraZeneca provides, "Covered Entity will hold title to replacement 340B Drugs from the time Supplier fills an order from Walgreens made on behalf of Covered Entity until the time that Walgreens takes delivery of such drugs at the applicable Pharmacy Location, at which time title shall pass to Walgreens." Agreement [31-1] at § 3.3.5. The Agreement defines "Supplier" as the drug manufacturer, supplier, or wholesaler "that has entered into a written agreement with Covered Entity to provide 340B Drugs to Walgreens via a

[3] Walgreen Co. is the parent company of Walgreens.
[4] AstraZeneca did not request the leave of Court before submitting additional evidence in support of its Motion. Nevertheless, the Court has, out of an abundance of caution considered the evidence.

ship-to, bill-to arrangement." *Id.* at § 2.20. The second provision highlighted by AstraZeneca states:

> None of the provisions of this Agreement are intended to create nor shall they be deemed or construed to create, any relationship between the parties hereto other than that of independent entities contracting solely for the purposes of effecting the provisions of this Agreement. Neither of the parties shall be construed to be the partner, co-venturer, or employee or representative of the other party.

Id. at § 8.10.

In *McClain*, the drug manufacturer argued that 340B "preempts the field because Congress intended to create a 'closed system' with the statute." 95 F.4th at 1144. The *McClain* court responded:

> This misconstrues what Act 1103 does. Pharmacies do not purchase 340B drugs, and they do not receive the 340B price discounts. Covered entities purchase and maintain title to the 340B-discounted drugs, while contract pharmacies dispense these drugs to covered entities' patients.

Id. (citing *Sanofi Aventis U.S. LLC*, 58 F.4th at 700). These declarations in the *McClain* decision derive from HRSA's 1996 Guidance, which explained that covered entities retain legal title to the 340B drugs, 61 Fed. Reg. at 43,552, while contract pharmacies become agents of the covered entity "with the authorization to 'dispense 340B drugs to patients of the covered entity pursuant to a prescription.'" *McClain*, 95 F.4th at 1142 (quoting 61 Fed. Reg. at 43,550).

AstraZeneca argues:

> The Walgreens Contract accordingly reinforces that (1) HB 728 is preempted by federal law because it purports to require AstraZeneca to charge 340B prices on sales to non-340B covered entities (contract pharmacies), in direct conflict with federal law; and (2) HB 728 violates the Takings Clause because it forces the transfer of private property

> (drugs at 340B prices) from one private party (AstraZeneca) to another (Walgreens, as a putative contract pharmacy).

Pl.'s Notice [31] at 2.

The Court finds these arguments unpersuasive for several reasons. First, AstraZeneca's Takings claim is not currently before the Court since AstraZeneca does not seek a preliminary injunction as to that claim. Second, the Walgreens Agreement is not evidence supporting preemption of Mississippi's H.B. 728 because it is an eight-year-old Arizona contract. And this is particularly true because there is no indication that the Mississippi Legislature intended to authorize, ratify, or otherwise condone contract pharmacy services agreements that violate 340B. *See* Miss. Code Ann. § 41-149-7(1) (prohibiting manufacturers or distributors from interfering with delivery of a 340B drug to a contract pharmacy "*unless* such receipt is prohibited by the United States Department of Health and Human Services") (emphasis added); *see also* Miss. Code Ann. § 41-149-11 ("Nothing in this chapter is to be construed or applied to be in conflict with" applicable federal law).

Third, if the language in any contract pharmacy services agreements violates 340B, HRSA can take enforcement action pursuant to the federal statute. Fourth, the Arizona Agreement does not call the Eighth Circuit's *McClain* decision into question. The covered entity's retention of title was only one basis for the *McClain* court's finding that the Arkansas statute was not preempted. For example, the *McClain* court also held, "Pharmacy 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." 95

F.4th at 1144. Finally, to the extent that AstraZeneca asserts that the Walgreens Agreement supports its prior [21] Motion for Expedited Discovery, the Court previously denied that Motion, and AstraZeneca has not sought reconsideration of its Motion. *See* L.U. Civ. R. 7(b)(1) ("Any written communication with the court that is intended to be an application for relief or other action by the court must be presented by a motion in the form prescribed by this rule.") Consequently, AstraZeneca's supplemental evidence does not tend support a finding of a substantial likelihood that AstraZeneca will succeed on the merits.

E. SUPPLEMENTAL AUTHORITY PROVIDED BY ASTRAZENECA

In its second [34] Notice of Supplemental Authority, AstraZeneca cites a recent district court decision enjoining enforcement of West Virginia Code § 60A-8-6a (hereafter called "S.B. 325") because its "No-Audits" and enforcement provisions are preempted by the federal 340B program. *Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, No. 2:24-CV-00271, 2024 WL 5147643 at *7, *12 (S.D.W. Va. Dec. 17, 2024). Since Mississippi's H.B. 728 does not contain a provision equivalent to S.B. 325's "No-Audits" provision, it is not necessary for this Court to address that portion of the *Morrisey* court's decision. The "No-Restrictions" provision" of S.B. 325, is very similar to Miss. Code Ann. § 41-149-7(1), but the *Morrisey* court did not reach the issue of whether the "No-Restrictions" provision was preempted because the "No-Restrictions" provision could not be severed from the remainder of the statute. *Morrisey*, 2024 WL 5147643, at *12.

S.B. 325's enforcement provision imposed penalties for violation of S.B. 325's "No-Restrictions" or "No-Audits" provisions. *Morrisey*, 2024 WL 5147643 at *3; *see also* W. Va. Code § 60A-8-6a(c) (brackets omitted). While considering whether S.B. 325's enforcement provision was preempted, the *Morrisey* decision found that this Court's prior decision in *Abbvie* was distinguishable due to insufficient discussion of: (1) "the potential impact" of United States Supreme Court's opinion in *Astra* on conflict preemption analysis; (2) the replenishment model; (3) H.B. 728's enforcement provisions; and (4) the basis for finding that H.B. 728 addresses delivery while Section 340B does not. *Id.* at *9, *11 (citing *Astra*, 563 U.S. at 118–20; *Abbvie*, 2024 WL 3503965, at *10–15).

In *Abbvie,* this Court distinguished the *Astra* decision because "[t]he Supreme Court's rejection of a right of action for covered entities under PPAs has minimal bearing on whether Section 340B preempts state law about the delivery of 340B drugs." *Abbvie*, 2024 WL 3503965, at *16 (quoting *Astra*, 563 U.S. at 118). Furthermore, a presumption against preemption applied in *Abbvie*, while no presumption applied in *Astra*. *See id.* This Court also rejected the drug manufacturer's argument that the replenishment model of distribution was grounds for finding preemption because the text of the federal 340B statute "does not prohibit distribution through contract pharmacies, and . . . distribution has long been understood not to constitute diversion." *See id.* at *5–6, *13–15.

Finally, this Court's determination that 340B does not address delivery was based on HRSA's 1996 Guidance as well as decisions by the Third Circuit, D.C.

Circuit, and Eighth Circuit that reached the same conclusion. *Id.* at *4–7, *10 (citing *Sanofi Aventis U.S. LLC*, 58 F.4th at 703; *McClain*, 95 F.4th at 1143; *Johnson*, 102 F.4th at 456–57; 1996 Guidance at 43,549–55). This Court explained:

> House Bill 728 does not require pharmaceutical manufacturers to offer 340B drugs below applicable ceiling prices, expand the definition of what a 340B healthcare provider is, or expand the remedies available to a covered entity when a manufacturer overcharges it for 340B drugs. House Bill 728 prohibits manufacturers from interfering with covered entities ordering delivery of Section 340B drugs to pharmacies for dispensation—something § 256b neither requires nor precludes.

Id. at *12.

After considering AstraZeneca's arguments and the District Court's decision in *Morrisey*, the Court finds that the analysis and reasoning in *Abbvie* are the more persuasive. Since the presumption against preemption applies here, AstraZeneca was required to demonstrate that it "was the clear and manifest purpose of Congress" to preempt Mississippi's regulation of the health and safety of its citizens when it enacted 340B. *See Deanda*, 96 F.4th at 761. Given this "high threshold," *Barrosse v. Huntington Ingalls, Inc.*, 70 F.4th 315, 320 (5th Cir. 2023), the Court finds that AstraZeneca has filed to demonstrate a substantial likelihood of success on the merits.

The Court finally notes that a majority of courts considering the issue have reached the same conclusion. *See, e.g. McClain*, 95 F.4th at 1146; *Pharm. Rsch. & Mfrs. of Am. v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597, at *8–9 (W.D. La. Sept. 30, 2024); *Novartis*, 2024 WL 3276407, at *7. Additionally, the United States Supreme Court has recently denied certiorari of the Eighth Circuit's decision in

McClain, rejecting a manufacturer's assertions of 340B preemption. *See Pharm. Rsch. v. McClain*, No. 24-118, 2024 WL 5011712 (U.S. Dec. 9, 2024). While this Court recognizes that the Supreme Court's denial of certiorari is not necessarily suggestive of its ultimate position on the issue, this Court is convinced that it would be imprudent to disregard mainstream decisions and the Eighth Circuit's ruling in *McClain* without clear precedential support.

II. THE REMAINING REQUIREMENTS FOR OBTAINING A PRELIMINARY INJUNCTION

Since AstraZeneca has not demonstrated a substantial likelihood of success on the merits as to any of its claims, it is not necessary for the Court to address the other preliminary injunction factors. *See Johnson v. Fed. Emergency Mgmt. Agency*, 393 F. App'x 160, 162 (5th Cir. 2010) (citing *La Union Del Pueblo Entero v. Fed. Emergency Mgmt. Agency*, 608 F.3d 217, 220 (5th Cir. 2010) (reversing grant of preliminary injunction, without considering all elements, because movant failed to show any likelihood of success on the merits)).

IT IS THEREFORE ORDERED AND ADJUDGED that Plaintiff AstraZeneca Pharmaceuticals LP's [13] Motion for Preliminary Injunction is **DENIED.**

SO ORDERED AND ADJUDGED this the 23rd day of December, 2024.

s/ *Louis Guirola, Jr.*

LOUIS GUIROLA, JR.
UNITED STATES DISTRICT JUDGE