KeyCite Blue-Striped Flag
Appeal Filed by Novartis Pharmaceuticals v. Fitch, 5th Cir., July 9, 2024

738 F.Supp.3d 737
United States District Court, S.D. Mississippi, Southern Division.

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff
v.
Lynn FITCH, in her official capacity as Attorney General of the State of Mississippi, Defendant

Civil No. 1:24-cv-164-HSO-BWR
|
Signed July 1, 2024

Synopsis
Background: Pharmaceutical manufacturer sought preliminary injunction in action against state attorney general, seeking declaration that recently-enacted state statute, which prohibited manufacturers from refusing to deliver to specified pharmacies drugs discounted under federal statute, which required drug manufacturers participating in Medicaid and Medicare Part B to provide certain drugs at discounted prices to certain healthcare providers, was preempted by federal law. Manufacturer moved for preliminary injunction.

Holdings: The District Court, Halil Suleyman Ozerden, J., held that:

[1] state statute was a law regulating health and safety falling within state's traditional police powers, and thus triggered presumption against federal preemption;

[2] state statute was not obstacle to execution of full purposes and objectives of federal statute, as would warrant application of conflict preemption;

[3] field preemption did not apply to state statute; and

[4] federal statute did not preempt state statute based on federal regulatory exclusivities.

Motion denied.

Procedural Posture(s): Motion for Preliminary Injunction.

West Headnotes (27)

[1] **Injunction** Grounds in general; multiple factors

A party seeking a preliminary injunction must show: (1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable harm if the injunction does not issue, (3) that the threatened injury outweighs any harm that will result if the injunction is granted, and (4) that granting the injunction is in the public interest. Fed. R. Civ. P. 65.

[2] **Injunction** Injunctions against government entities in general

The balance-of-harms and public-interest factors evaluated when a party seeks a preliminary injunction merge when the government opposes an injunction. Fed. R. Civ. P. 65.

[3] **Injunction** Extraordinary or unusual nature of remedy

Injunction Grounds in general; multiple factors

Injunction Clear showing or proof

A preliminary injunction is an extraordinary remedy and should be granted only if the movant has clearly carried the burden of persuasion with respect to all four factors a movant is required to address in seeking a preliminary injunction. Fed. R. Civ. P. 65.

[4] **Federal Preemption** Federal Preemption

Under the principles articulated in the Supremacy Clause, Congress has the power to preempt state law. U.S. Const. Art. 6, cl. 2.

[5] **Federal Preemption** Congressional Intent or Purpose

When a party raises preemption as a basis to challenge state law, the purpose of Congress is the ultimate touchstone of the analysis.

[6] Federal Preemption 🔑 Construction of statute in general

Preemption of state law may be compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.

[7] Federal Preemption 🔑 Presumptions and burden of proof

The court cannot assume lightly that Congress has derogated state regulation, but instead should address claims of preemption with the starting presumption that Congress does not intend to supplant state law.

[8] Federal Preemption 🔑 Presumptions and burden of proof

Deference to federalism counsels a presumption that areas of law traditionally reserved to the states are not to be disturbed by preemption absent the clear and manifest purpose of Congress.

[9] Federal Preemption 🔑 Grounds for preemption in general

Three categories of preemption exist: 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).

[10] Federal Preemption 🔑 Impossibility of complying with both state and federal law

Federal Preemption 🔑 State law as obstacle to objectives or purpose of federal law

“Conflict preemption” arises where compliance with both state and federal law is impossible, or where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress; in either situation, federal law must prevail.

[11] Federal Preemption 🔑 State law as obstacle to objectives or purpose of federal law

A party claiming application of conflict preemption on a theory that state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress must show that the state law produces a result inconsistent with the objective of the federal statute; such a party must meet a high threshold to succeed on such a theory.

[12] Federal Preemption 🔑 Conflicting or Conforming Laws or Regulations; Conflict Preemption

Courts, in deciding whether to apply conflict preemption, may not conduct a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives, because such an endeavor would undercut the principle that it is Congress rather than the courts that preempts state law.

[13] Federal Preemption 🔑 Traditionally or historically regulated by states

Federal Preemption 🔑 Presumptions and burden of proof

In a case involving conflict preemption of a state law regulating health and safety, preemption analysis begins with the assumption that the historic police powers of the states are not to be superseded by the federal act unless that was the clear and manifest purpose of Congress; that is because a state law regulating health and safety falls within a state's traditional police powers.

[14] Antitrust and Trade Regulation 🔑 Preemption

Federal Preemption 🔑 Health

State statute was a law regulating health and safety falling within state's traditional police powers, and thus triggered presumption against federal preemption, where state statute prohibited pharmaceutical manufacturers from refusing to deliver to specified pharmacies drugs discounted pursuant to federal statute, which required manufacturers who participate in Medicaid and Medicare Part B to provide certain drugs at discounted prices, presumably to maximize covered-entity patients' access to drugs for which the manufacturers have already agreed to provide a discount. Public Health Service Act § 340B, 42 U.S.C.A. § 256b.

1 Case that cites this headnote
More cases on this issue

[15] **Federal Preemption** Torts

Fraud Nature and form of remedy

In the context of a conflict-preemption analysis with respect to state-law tort claims based on fraud against a federal agency, the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.

[16] **Antitrust and Trade Regulation** Preemption

Federal Preemption Health

Federal statute requiring manufacturers participating in Medicaid and Medicare Part B to provide certain drugs at discounted prices did not exhibit clear purpose to preempt state laws that required manufacturers to deliver such drugs to specified pharmacies for distribution, and thus state statute prohibiting manufacturers from refusing to deliver such drugs to specified pharmacies was not obstacle to execution of objectives of federal statute warranting application of conflict preemption; state statute was law regulating health and safety subject to presumption against preemption, federal statute did not explicitly mandate how delivery of discounted drugs must occur, but merely required manufacturers to offer each covered entity covered outpatient drugs at discounted price, and there was no clear evidence of actual, significant conflict, as federal statute did not implicitly preclude state from taking such action. Public Health Service Act § 340B, 42 U.S.C.A. § 256b.

1 Case that cites this headnote
More cases on this issue

[17] **Federal Preemption** Federal administrative regulations

Federal Preemption Congressional Intent or Purpose

Federal law can preempt state law when Congress, or a federal agency implementing federal law, makes a policy choice that balances competing objectives in such a way that a state regulation aimed at the same subject matter upsets the balance that the federal government struck.

[18] **Antitrust and Trade Regulation** Preemption

Federal Preemption Health

State statute prohibiting manufacturers from refusing to deliver drugs discounted under federal statute to specified pharmacies did not erect substantial obstacle to centralized federal enforcement process under federal statute requiring drug manufacturers participating in Medicaid and Medicare Part B to provide certain drugs at discounted prices by creating separate enforcement pathway before state administrative agencies, and thus its alleged impact on enforcement would not support a finding of conflict preemption; state statute addressed delivery of such drugs and federal statute did not, so adjudications under state statute would not interfere with federal enforcement of compliance mechanisms under federal statute. Public Health Service Act § 340B, 42 U.S.C.A. § 256b.

More cases on this issue

[19] **Antitrust and Trade Regulation** Preemption
Federal Preemption Health

Congress had not precluded state from enacting its own policy governing delivery of drugs subject to mandatory discounts under federal statute requiring drug manufacturers participating in Medicaid and Medicare Part B to provide certain drugs at discounted prices, and thus field preemption did not apply to state statute prohibiting manufacturers from refusing to deliver drugs discounted under federal statute to specified pharmacies; state statute was law regulating health and safety, triggering presumption against preemption, and federal statute did not control how manufacturers must deliver discounted drugs to patients of covered entities, leaving room for states to impose their own regulations on delivery of such drugs to promote patients' access to their medications. Public Health Service Act § 340B, 42 U.S.C.A. § 256b.

1 Case that cites this headnote
More cases on this issue

[20] **Federal Preemption** Occupation of field; field preemption

"Field preemption" requires that Congress has passed such comprehensive legislation in an area that it has occupied the field.

[21] **Federal Preemption** Occupation of field; field preemption

Congress's intent to displace state law, as would support application of field preemption, can be inferred from its enactment of a federal regulatory scheme 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.

[22] **Federal Preemption** Occupation of field; field preemption

Field preemption of state should not be inferred simply because a federal agency's regulations are comprehensive.

[23] **Federal Preemption** Occupation of field; field preemption

Field preemption of state law is disfavored.

[24] **Federal Preemption** Occupation of field; field preemption

Field preemption is not to be found where federal regulations, while detailed, appear to contemplate some concurrent state regulation.

[25] **Antitrust and Trade Regulation** Preemption
Federal Preemption Health

Merely because the federal statute requiring pharmaceutical manufacturers who participate in Medicare Part B and Medicaid to provide discounts to certain healthcare providers is sufficiently comprehensive to meet the need identified by Congress does not mean that states and localities are barred from identifying additional needs or imposing further requirements in the field. Public Health Service Act § 340B, 42 U.S.C.A. § 256b.

[26] **Antitrust and Trade Regulation** Preemption
Federal Preemption Health

Federal prescription drug laws, including those governing regulatory exclusivity and patent protection periods, did not preempt state statute prohibiting manufacturers from refusing to deliver to specified pharmacies drugs discounted under federal statute, which required drug manufacturers participating in Medicaid and Medicare Part B to provide certain drugs at discounted prices, based on federal regulatory exclusivities; federal statute did not impose discounts on drugs beyond those for which manufacturers have already agreed to provide discounts in order to participate in Medicare Part B and Medicaid, and because state statute did not purport to lower prices on drugs not already discounted under federal statute, it did not substantially interfere with incentives created by patent laws or other federal laws establishing regulatory exclusivities. Public Health Service Act § 340B, 42 U.S.C.A. § 256b.

1 Case that cites this headnote
More cases on this issue

[27] **Federal Preemption** Patents
Patents Preemption

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.

1 Case that cites this headnote

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MEMORANDUM OPINION AND ORDER DENYING MOTION [4] FOR PRELIMINARY INJUNCTION

HALIL SULEYMAN OZERDEN, UNITED STATES DISTRICT JUDGE

This matter comes before the Court on Plaintiff Novartis Pharmaceuticals Corporation's ("Novartis" or "Plaintiff") Motion [4] for Preliminary Injunction. Having considered the allegations set forth in Plaintiff's Complaint [1], the parties' Memoranda [5], [12], [27], and relevant legal authority, and having heard argument at a ***742** hearing held on June 27, 2024, the Court will deny the Motion [4].

I. BACKGROUND

Plaintiff's Motion [4] asks the Court to enjoin the enforcement of Mississippi's recently enacted "Defending Affordable Prescription Drug Costs Act," 2024 Miss. H.B. 728 ("H.B. 728"), which is set to take effect on July 1, 2024. House Bill 728 concerns a federal program referred to as Section 340B. *See* 42 U.S.C. § 256b. Under Section 340B, pharmaceutical manufacturers who participate in Medicaid and Medicare Part B must offer certain drugs at discounted prices to certain healthcare providers, called "covered entities," that generally provide care for the poor. *See infra*, Part I.A. In essence, H.B. 728 requires manufacturers to deliver drugs ordered through the 340B program to for-profit pharmacies called "contract pharmacies" with which covered entities have arrangements under which the pharmacy will dispense discounted drugs to the covered entity's patients.

Plaintiff claims that H.B. 728, in requiring it to deliver discounted drugs to an unlimited number of contract pharmacies, invalidly expands its obligation to provide discounted drugs to covered entities. *See id.* at 2, 6–7. It asserts that H.B. 728 is preempted by § 256b and various federal laws—such as patent laws—that provide regulatory exclusivities that enable manufacturers to reap high profits as incentives for innovation in pharmaceuticals. *See id.* at 1–3. Plaintiff therefore seeks a preliminary injunction to stay the enforcement of H.B. 728. Because it is unable to satisfy the necessary elements for such relief, Plaintiff's Motion [4] will be denied.

A. The Section 340B program

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*, No. 21-3167, 2023 WL 1325507 (3d Cir. Jan. 30, 2023). Those healthcare providers are "called '340B' or 'covered' entities," and "include public hospitals and community health centers, many of" which are "providers of safety-net services to the poor." *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 113, 131 S.Ct. 1342, 179 L.Ed.2d 457 (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"). *Id.*

"Drug manufacturers," such as Plaintiff, "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." § 256b(a)(1).

Through Section 340B, Congress leverages the federal government's market power in 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 ***743** 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)).

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." § 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* § 256b(a)(5)(A)(i).

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

§ 256b(a)(5)(C). And "[i]f 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." § 256b(a)(5)(D).

The Secretary can impose additional sanctions. Covered entities that the Secretary finds knowingly and intentionally resold discounted drugs must "pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under [§ 256(a)(5)(D)]." § 256b(d)(2)(B)(v)(I). Where the Secretary finds the covered entity's reselling "was systematic and egregious as well as knowing and intentional," the Secretary can remove the covered entity from the program entirely. § 256b(d)(2)(B)(v)(II).

B. <u>The dispensation of 340B drugs at contract pharmacies and related litigation</u>

The issue in this case concerns a matter notably absent from the foregoing discussion: how discounted drugs under Section 340B are to be delivered to patients of covered entities.

Between 1996 and March 2010, HRSA's 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 Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,549–50 (Aug. 23, 1996) ("1996 Guidance")). Given that "many covered entities use outside pharmacies to distribute drugs to their patients," HRSA's 1996 Guidance "stated that a covered entity ***744** without an in-house pharmacy may contract with a single outside pharmacy to dispense drugs at a single location." *Id.* at 457 (citing 1996 Guidance at 43,555). The 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 1996 Guidance at 43,553).

In 2010, HRSA shifted course. 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." *Id.* (citing Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010) ("2010 Guidance")). In its view, this Guidance "would permit covered entities to more effectively utilize 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. 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), 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. But 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, 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 Plaintiff argues in its Memorandum [5], pharmaceutical manufacturers were and remain concerned about the model covered entities and contract pharmacies often use in dispensing and accounting for Section 340B drugs. *See* Memo [5] at 14–15. Plaintiff refers to that model as the "replenishment model." *Id.* Put simply, under this model, a contract pharmacy first dispenses prescription drugs to all its customers from one supply of drugs, which it purchased at full price from the manufacturer. *Id.* According to Plaintiff, the pharmacy—or a third-party administrator—determines whether a customer was a covered-entity patient after it dispenses the drug "based on an opaque formula generally not shared with manufacturers." *Id.* The pharmacy then informs the covered entity of the quantity of drugs it dispensed to the entity's patients. *Id.* The covered entity then places an order of Section 340B drugs in that quantity as a "replenishment" of the drugs dispensed to covered-entity patients. *See id.*

As the D.C. Circuit recognized, "[m]anufacturers," such as Plaintiff, "have argued that these arrangements lead to unlawful diversion and duplicate discounts." *Novartis*, 102 F.4th at 458. 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 ***745** as eligible for the discount." *Id.* at 457–58.

In 2020, HHS, concerned about manufacturers' policies limiting covered-entity patients' access to medications, issued an advisory opinion stating that pharmaceutical manufacturers are *required* to ship Section 340B drugs 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 ("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 Third Circuit and 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. For example, 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)). An association of pharmaceutical manufacturers sought an injunction against enforcement of the Arkansas law on a theory that Section 340B preempts it. *Id.* at 1139–40. The Eighth Circuit, however, 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 " 'is silent about delivery' of drugs to patients." *Id.* at 1143 (quoting *Sanofi Aventis U.S. LLC*, 58 F.4th at 703) (other quotation marks and citation omitted). 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.*

On April 12, 2024, the Governor of Mississippi signed H.B. 728, which had been enacted by the state legislature. Ex. [12-1] (H.B. 728). House Bill 728 provides that "[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." H.B. 728 § 4. The law defines a "340B drug" as a covered outpatient drug "that has been subject to any offer for reduced prices by a manufacturer pursuant to [Section 340B]." H.B. 728 § 2(a). A violation of H.B. 728 constitutes a violation of the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1 *et seq.*, *see* H.B. 728 § 5, which provides for ***746** both civil and criminal penalties and is enforced by Mississippi's Attorney General, *see* Miss Code Ann. §§ 75-24-9 (covering injunctive relief), 75-24-19 (covering civil penalties for violations of injunctions issued under § 75-24-9, and for knowing and willful violations of the statute), 75-24-20 (covering criminal penalties for knowing and willful violations).

C. Procedural history

On June 3, 2024, Plaintiff Novartis Pharmaceuticals Corporation filed a Complaint [1] in this Court seeking a declaratory judgment under 28 U.S.C. § 2201 that H.B. 728 is preempted by federal law. Compl. [1] at 24. It likewise sought temporary, preliminary, and permanent injunctive relief against the Attorney General of Mississippi, enjoining her from enforcing H.B. 728 against Plaintiff. *Id.* at 25. Plaintiff filed a Motion [4] for Preliminary Injunction on June 4, 2024, and argues that H.B. 728 is preempted under conflict and field preemption. *See generally* Memo [5]. Defendant, Mississippi Attorney General Lynn Fitch, ("Defendant") responded on June 17, 2024, Resp. [11], and the American Hospital Association, 340B Health, the Mississippi Hospital Association, and the Rural Hospital Alliance filed an Amicus Brief [17] on June 18, 2024, in support of Defendant. The Court held a hearing on the Motion [4] on June 27, 2024.

II. DISCUSSION

[1] **[2]** **[3]** A party seeking a preliminary injunction must show: "(1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable harm if the injunction does not issue, (3) that the threatened injury outweighs any harm that will result if the injunction is granted, and (4) that granting the injunction is in the public interest." *Clarke v. Commodity Futures Trading Comm'n*, 74 F.4th 627, 640–41 (5th Cir. 2023); *see* Fed. R. Civ. P. 65. Factors three and four, "[t]he balance-of-harms and public-interest factors[,] merge when the government opposes an injunction." *Career Colleges & Sch. of Texas v. United States Dep't of Educ.*, 98 F.4th 220, 254 (5th Cir. 2024) (citing *Nken v. Holder*, 556 U.S. 418, 435, 129 S.Ct. 1749, 173 L.Ed.2d 550 (2009)). "A preliminary injunction is an extraordinary remedy and should be granted only if the movant has clearly carried the burden of persuasion with respect to all four factors." *Allied Mktg. Grp., Inc. v. CDL Mktg., Inc.*, 878 F.2d 806, 809 (5th Cir. 1989).

Plaintiff cannot satisfy the first requirement because it has not demonstrated a "substantial likelihood of success on the merits." *Clarke*, 74 F.4th at 640. The Court will therefore deny the Motion [4] and need not reach the other elements.

A. Preemption generally

[4] The Supremacy Clause of the United States Constitution provides that federal law "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." Art. VI, cl. 2. "Under this principle, Congress has the power to preempt state law." *Arizona v. United States*, 567 U.S. 387, 399, 132 S.Ct. 2492, 183 L.Ed.2d 351 (2012).

[5] **[6]** **[7]** **[8]** When a party raises preemption, " '[t]he purpose of Congress is the ultimate touchstone' of [the] analysis." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504, 98 S.Ct. 1185, 55 L.Ed.2d 443 (1978)) (other citations and quotations omitted). Preemption may be "compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." ***747** *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383, 112 S.Ct. 2031, 119 L.Ed.2d 157 (1992) (internal quotation marks and citation omitted). But the Court cannot "assume[ ] lightly that Congress has derogated state regulation, but instead [should] address[ ] claims of pre-emption with the starting presumption that Congress does not intend to supplant state law." *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655, 115 S.Ct. 1671, 131 L.Ed.2d 695 (1995). And "[d]eference to our federalism counsels a presumption that areas of law traditionally reserved to the states ... are not to be disturbed absent the clear and manifest purpose of Congress." *In re Davis*, 170 F.3d 475, 481 (5th Cir. 1999) (en banc) (internal quotation marks and citations omitted).

[9] Three categories of preemption exist: "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) (citing *Arizona*, 567 U.S. at 398–400, 132 S.Ct. 2492). Plaintiff does not contend that the 340B Program, or federal drug laws that provide regulatory and patent exclusivity periods, expressly preempt Mississippi law. *See generally* Memo [5]. Rather, Plaintiff argues that the 340B Program implicitly preempts Mississippi law under conflict preemption and field preemption, *id.* at 22–28, and that Mississippi law conflicts with federal drug laws that provide regulatory and patent exclusivity periods, *id.* at 28–31.

B. Section 340B does not preempt H.B. 728 under conflict preemption

[10] Conflict preemption arises "where 'compliance with both state and federal law is impossible,' or where 'the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 377, 135 S.Ct. 1591, 191 L.Ed.2d 511 (2015) (quoting *California v. ARC America Corp.*, 490 U.S. 93, 100, 101, 109 S.Ct. 1661, 104 L.Ed.2d 86 (1989)) (other internal quotation marks omitted). "In either situation, federal law must prevail." *Id.*

[11] **[12]** Plaintiff does not contend that compliance with both Mississippi and federal law is impossible. *See generally* Memo [5]. So, Plaintiff must show that Mississippi law "produce[s] a result inconsistent with the objective of the federal statute," *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947), such that it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S.Ct. 399, 85 L.Ed. 581 (1941). Plaintiff must meet "a high threshold" to succeed on such a theory. *Barrosse v. Huntington Ingalls, Inc.*, 70 F.4th 315, 320 (5th Cir. 2023) (quoting *Chamber of Com. v. Whiting*, 563 U.S. 582, 607, 131 S.Ct. 1968, 179 L.Ed.2d 1031 (2011)), *cert. denied*, ––– U.S. ––––, 144 S. Ct. 557, 217 L.Ed.2d 296 (2024). "Courts may not conduct 'a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives [because] such an endeavor would undercut the principle that it is Congress rather than the courts that pre-empts state law.' " *Id.* (quoting *Whiting*, 563 U.S. at 607, 131 S.Ct. 1968) (alteration in original).

[13] In a case like this one, "[p]reemption analysis begins 'with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.' " ***748** *Deanda*, 96 F.4th at 761 (quoting *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77, 129 S.Ct. 538, 172 L.Ed.2d 398 (2008)). That is because 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, 105 S.Ct. 2371, 85 L.Ed.2d 714 (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"); *Elam v. Kansas City S. Ry. Co.*, 635 F.3d 796, 813 (5th Cir. 2011) (discussing how the Court should "begin with the assumption that Congress did not intend to supersede the historic police powers of the states to protect the health and safety of their citizens" (internal quotation marks and citation omitted)).

[14] House Bill 728 plainly falls under the umbrella of a health and safety regulation. 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. The state statute therefore triggers the presumption against preemption. *See Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 666, 123 S.Ct. 1855, 155 L.Ed.2d 889 (2003) (plurality opinion of Stevens, J.) (applying "[t]he presumption against federal pre-emption of a state statute designed to foster public health" (citing *Hillsborough Cnty.*, 471 U.S. at 715–18, 105 S.Ct. 2371), and rejecting a preemption claim challenging a Maine policy that subjected drug manufacturers' pharmaceuticals to prior authorization procedures before providing state Medicaid coverage for them unless the manufacturers agreed to provide rebates to Maine residents beyond rebates the Medicaid Act provides for); *Wyeth v. Levine*, 555 U.S. 555, 578, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009) ("[T]he FDA traditionally regarded state law as a complementary form of drug regulation."); *McClain*, 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").

Plaintiff argues that the law does not trigger this presumption, but the Court is unpersuaded. *See* Reply [27] at 2. Plaintiff cites *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372 (5th Cir. 2012), to assert that "the Supreme Court has often declined to apply the presumption in its conflict-preemption analysis." *Id. Lofton* merely states that "whatever value or relevance a presumption against preemption of state tort law should play is uncertain" given its observation that the Supreme Court's "majority opinion in [*PLIVA, Inc. v. Mensing*, 564 U.S. 604, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011)] made no reference to the 'presumption' in the course of upholding implied conflict preemption over state law claims for failure to maintain adequate warning labels for FDA-approved generic drugs." 672 F.3d at 378. *Lofton*'s statements about the scope of the presumption against preemption do not mean that the presumption against preemption no longer applies.

***749** **[15]** Further, *Lofton*'s statement that "the primacy of the state's police powers is not universal" is inapplicable here. *Id. Lofton* discussed state-law tort claims based on fraud on the FDA. *See id.* at 378–79. In that context, "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 378 (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001)). House Bill 728 does not purport to prohibit fraud on a federal agency.

[16] Applying the presumption against preemption here, the Court does not find that Section 340B exhibits a clear purpose to preempt state laws that would require manufacturers to deliver covered entities' drugs to contract pharmacies for distribution. Section 340B does not explicitly mandate how delivery of discounted drugs is to occur. *See McClain*, 95 F.4th at 1142 ("[T]he 340B Program 'is silent about delivery' and distribution of pharmaceuticals to patients." (quoting *Sanofi Aventis*, 58 F.4th at 703)).[1] Section 340B merely requires participating manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." § 256b(a)(1).

Sanofi Aventis and *Novartis* concluded that, under the terms of Section 340B, HHS may not *require* manufacturers to ship drugs intended for covered-entity patients to any contract pharmacy the entity deals with. *Sanofi Aventis*, 58 F.4th at 703 (concluding that "Section 340B does not require delivery to an unlimited number of contract pharmacies"); *Novartis*, 102 F.4th at 460–63. But the same "[s]tatutory silence[ ]," *Sanofi Aventis*, 58 F.4th at 699, that does not *implicitly mandate* that manufacturers deliver to any contract pharmacy does not, on the other hand, show that Congress clearly intended to *preclude states* from enacting their own public health regulations aimed at maximizing the availability of low-cost drugs for covered-entity patients, *see McClain*, 95 F.4th at 1145 (concluding that "the delivery of a covered entity's 340B drugs to contract pharmacies for dispensing creates no obstacle" to Section 340B's objectives). If anything, H.B. 728 arguably promotes Section 340B's objective of ensuring covered-entity patients can conveniently access their medications. *See id.* at 1144–45 (explaining how Arkansas's prohibition on manufacturers preventing covered entities from contracting with pharmacies for drug distribution "does not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite: [the law] assists in fulfilling the purpose of 340B").

[17] The upshot of Plaintiff's argument is that Congress deliberately left to pharmaceutical manufacturers the discretion to refuse to ship 340B discounted drugs to contract pharmacies simply because it was silent in the statute about delivery. *See* Reply [27] at 4 (citing *Novartis*, 102 F.4th at 460). Plaintiff is correct that federal law can preempt state law when Congress, or a federal agency implementing federal law, makes a policy choice that balances competing objectives in such a way that a state regulation aimed at the same subject matter ***750** upsets the balance that the federal government struck. *See* Memo [5] at 26 (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000)). But that is not this case.

In *Geier*, the Court held that a Department of Transportation regulation, FMVSS 208, requiring automobile manufacturers to equip some, but not all, of their 1987 vehicles with passive restraints—such as airbags—preempted state tort law requiring airbags beyond what that regulation required. 529 U.S. at 864–65, 120 S.Ct. 1913. But there, the Supreme Court found that "clear evidence of a conflict" existed between state tort law and the regulation. *Id.* at 885, 120 S.Ct. 1913. The Court reached this conclusion based on the agency's "contemporaneous explanation" of several "significant considerations" it had in mind in designing the regulation. *See id.* at 877–81, 120 S.Ct. 1913. The regulation "deliberately provided [car manufacturers] with a range of choices among different passive restraint devices," so as to "lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance." *Id.* at 875, 120 S.Ct. 1913.

Here, Plaintiff does not persuasively show, at least at this stage of the proceedings, how H.B. 728 creates a substantial obstacle to Section 340B's purposes, or what consideration Congress had in mind in not addressing delivery of 340B drugs. In other words, there is no clear evidence of an "actual," "significant" conflict. *Id.* at 884–85, 120 S.Ct. 1913 (internal quotation marks and citation omitted). 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 distribution —something Section 340B may not require, but does not implicitly preclude either.

To the extent that delivering discounted drugs to contract pharmacies raises the risk of diversion, Section 340B prohibits diversion and provides for comprehensive enforcement mechanisms. *See supra*, Part I.A. If Section 340B healthcare providers are conspiring with pharmacies to divert discounted drugs, HHS can require the provider to compensate the manufacturer for its losses, § 256b(a)(5), and remove the provider from the program, § 256b(d)(2)(B)(v)(II). The Court is not prepared to find Section 340B likely preempts H.B. 728 on a theory that Congress's remedial scheme under Section 340B is inadequate to deter violations of federal law. As written, H.B. 728 and Section 340B do not conflict.

Congress also increased enforcement mechanisms against diversion in the Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 7102, 124 Stat. 119 (enacted March 23, 2010), by adding § 256b(d), *id.* at 823–26, 18 days after the 2010 HRSA Guidance that advised that covered entities can use an unlimited number of contract pharmacies, Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010). Thus, Congress was presumably aware of the potential for diversion through the use of an unlimited number of contract pharmacies, and it increased enforcement against diversion, yet remained silent about delivery—not to mention about preemption. And while "failures to enact legislation 'are not reliable indicators of congressional intent,' " *Novartis*, 102 F.4th at 462 (quoting ***751** *Mead Corp. v. Tilley*, 490 U.S. 714, 723, 109 S.Ct. 2156, 104 L.Ed.2d 796 (1989)), Plaintiff's argument relies on an inference of preemptive intent from Congress's silence as to delivery, so the Court considers legislative context relevant in interpreting that silence, *see Arizona*, 567 U.S. at 405–406, 132 S.Ct.

2492 (discussing policy proposals Congress did not enact in analyzing preemption).

[18] In addition, Plaintiff argues that "H.B. 728 erects a substantial obstacle to that centralized federal process" for enforcing Section 340B's requirements "by creating its own enforcement pathway before state administrative agencies." Memo [5] at 27. The Court disagrees: H.B. 728 addresses delivery and Section 340B does not, so adjudications under H.B. 728 will not interfere with federal enforcement of Section 340B's compliance mechanisms. The Court therefore concludes that Plaintiff has not shown a substantial likelihood that it will succeed on the merits of its conflict-preemption claim.

C. Section 340B does not preempt H.B. 728 under field preemption

[19] **[20]** **[21]** **[22]** The Court is also unpersuaded that Section 340B preempts H.B. 728 under a theory of field preemption. Field preemption requires that Congress has passed such comprehensive legislation in an area that it has "occupied the field." *Arizona*, 567 U.S. at 401, 132 S.Ct. 2492. Congress's intent to displace state law can be inferred from its enactment of a federal regulatory scheme " '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.' " *Id.* at 399, 132 S.Ct. 2492 (quoting *Rice*, 331 U.S. at 230, 67 S.Ct. 1146). Field preemption "should not be inferred, however, simply because the agency's regulations are comprehensive." *R.J. Reynolds Tobacco Co. v. Durham Cnty., N.C.*, 479 U.S. 130, 149, 107 S.Ct. 499, 93 L.Ed.2d 449 (1986).

[23] **[24]** "Field preemption of state law is disfavored." *Nat'l Press Photographers Ass'n v. McCraw*, 90 F.4th 770, 796 (5th Cir. 2024). The Fifth Circuit has emphasized that "Courts should not infer field preemption in 'areas that have been traditionally occupied by the states,' in which case congressional intent to preempt must be 'clear and manifest.' " *Id.* (citing *English v. Gen. Elec. Co.*, 496 U.S. 72, 79, 110 S.Ct. 2270, 110 L.Ed.2d 65 (1990)). "And importantly, field preemption is not to be found where federal 'regulations, while detailed, appear to contemplate some concurrent state regulation.' " *Id.* (quoting *R.J. Reynolds Tobacco*, 479 U.S. at 149, 107 S.Ct. 499).

[25] House Bill 728 implicates a traditional area of state regulation, triggering the presumption against preemption, *see supra*, Part II.B., and rendering inapplicable *Arizona*'s discussion of dominant federal interests, *see Arizona*, 567 U.S. at 399, 132 S.Ct. 2492. Section 340B also does not control how manufacturers must deliver discounted drugs to patients of covered entities. *See supra*, Part II.B. Section 340B thus leaves room for states to impose their own regulations on delivery of Section 340B drugs to promote patients' access to their medications. "[M]erely because [Section 340B is] sufficiently comprehensive to meet the need identified by Congress [does] not mean that States and localities [are] barred from identifying additional needs or imposing further requirements in the field." *Hillsborough Cnty.*, 471 U.S. at 717, 105 S.Ct. 2371. While federal law comprehensively regulates the determination of ceiling prices on Section 340B drugs and provides robust enforcement ***752** mechanisms that ensure covered entities and manufacturers comply with the statute's requirements, *see supra*, Part I.A., Congress has not precluded Mississippi from enacting its own policy governing delivery of Section 340B drugs.

The Court is also not persuaded that field preemption is compelled by *Astra*'s holding that covered entities cannot bring overcharging claims as third-party beneficiaries to PPAs. *See Astra*, 563 U.S. at 117–19, 131 S.Ct. 1342. *Astra* rejected an argument that, despite a covered entity's "inability to assert a statutory right of action" under Section 340B itself, "PPAs implementing the 340B Program are agreements enforceable by covered entities as third-party beneficiaries." *Astra*, 563 U.S. at 117, 131 S.Ct. 1342. Because PPAs are essentially contracts whereby manufacturers opt into Section 340B, the Court reasoned that "[a] third-party suit to enforce an HHS-drug manufacturer agreement, therefore, is in essence a suit to enforce the statute itself." *Id.* at 118, 131 S.Ct. 1342. Accordingly, "[t]he absence of a private right to enforce the statutory ceiling-price obligations would be rendered meaningless if 340B entities could overcome that obstacle by suing to enforce the contract's ceiling-price obligations instead." *Id.*

The 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. And *Astra* did not apply any presumption in favor of such a right of action analogous to the presumption against preemption applicable here. *See Arizona*, 567 U.S. at 400, 132 S.Ct. 2492 ("In preemption analysis, courts should assume that the historic police powers of the States are not superseded unless that was the clear and manifest purpose of Congress." (internal quotation marks and citations omitted)).

The Court therefore concludes that Plaintiff has not shown a substantial likelihood of success on the merits of its field preemption claim.

D. Federal laws that provide regulatory exclusivities do not preempt H.B. 728

[26] Plaintiff next contends that H.B. 728 "is preempted by federal drug laws, including those governing regulatory exclusivity and patent protection periods." Memo [5] at 28. The Court disagrees.

[27] The patent laws and other regulatory exclusivities cited by Plaintiff, including the Food, Drug, and Cosmetic Act and Hatch-Waxman Act, create bargains whereby, "[i]n exchange for bringing new designs and technologies into the public domain through disclosure ... an inventor receives a limited term of protection from competitive exploitation." *Amgen Inc. v. Sanofi*, 598 U.S. 594, 604, 143 S.Ct. 1243, 215 L.Ed.2d 537 (2023) (internal quotations and citations omitted). 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." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480, 94 S.Ct. 1879, 40 L.Ed.2d 315 (1974) (quoting *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 231, 84 S.Ct. 784, 11 L.Ed.2d 661 (1964)). Plaintiff asserts, and the Court assumes, that the same logic applies to preemption claims based on other federal regulatory exclusivities that incentivize innovation in pharmaceuticals; that is, that state laws capping prices on drugs that federal law insulates from competition interfere with the objectives of federal law. *See* Memo [5] at 30 (citing *Biotechnology Indus. Org. v. D.C.*, 496 F.3d 1362, 1374 (Fed. Cir. 2007) (concluding that, "[b]y penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—the ***753** District has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs")).

Section 340B does not impose discounts on drugs beyond those for which manufacturers have already agreed to provide discounts in order to participate in Medicare Part B and Medicaid. *See supra*, Part I.A. Because H.B. 728 does not purport to lower prices on any drugs not already discounted under Section 340B, it does not substantially interfere with the incentives created by patent laws or other federal laws establishing regulatory exclusivities. The Court therefore does not find that Plaintiff has shown a substantial likelihood of success on the merits of its preemption claim based on federal regulatory exclusivities.

III. CONCLUSION

Because Plaintiff has not shown a substantial likelihood of success on the merits as required to obtain a preliminary injunction, it is not entitled to such relief, and the Court need not address the remaining Rule 65 factors. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 23–24, 129 S.Ct. 365, 172 L.Ed.2d 249 (2008) (declining to address other preliminary injunction factors after finding against the plaintiffs on one such factor). To the extent the Court has not addressed any of the parties' remaining arguments, it has considered them and determined they would not alter the Court's conclusion.

IT IS, THEREFORE, ORDERED AND ADJUDGED THAT, Plaintiff Novartis Pharmaceuticals Corporation's Motion [4] for Preliminary Injunction is **DENIED.**

SO ORDERED AND ADJUDGED, this the 1st day of July, 2024.

All Citations

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Footnotes

1 Section 340B discusses 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, "*If* a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution." § 256b(a)(8) (emphasis added). These provisions do not mandate how delivery is to occur.

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