United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
April 9, 2026
Lyle W. Cayce
Clerk

No. 24-60342

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff—Appellant,

versus

LYNN FITCH, *in her official capacity as Attorney General of the State of Mississippi*,

Defendant—Appellee.

Appeal from the United States District Court
for the Southern District of Mississippi
USDC No. 1:24-CV-164

Before KING, HO, and RAMIREZ, *Circuit Judges*.

PER CURIAM:[*]

Novartis Pharmaceuticals Corporation appeals the denial of its motion to preliminarily enjoin the enforcement of a state law governing the distribution of drugs that are discounted under a federal program. It contends that the state law is preempted by federal law. We AFFIRM.

[*] This opinion is not designated for publication. *See* 5TH CIR. R. 47.5.

I

Section 340B of the Public Health Service Act requires drug manufacturers that participate in Medicaid and Medicare Part B, like Novartis, to offer covered outpatient drugs at discounted prices to specified "covered entities," such as eligible nonprofit and public hospitals, community health centers, and clinics. 42 U.S.C. §§ 256b(a)(1), (a)(4). The Health Resources and Services Administration, which administers the Section 340B program, has interpreted the statute to permit covered entities to dispense 340B priced drugs to their patients through pharmacies with which they contract. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549, 43549 (Aug. 23, 1996); Notice Regarding 340B Drug Pricing Program–Contract Pharmacy Services, 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010). The statute prohibits covered entities from diverting discounted drugs by reselling or transferring them to nonpatients and from obtaining duplicate discounts through receipt of both Section 340B discounts and Medicaid rebates for the same drug. 42 U.S.C. §§ 256b(a)(5), (b)(2).

Many participating drug manufacturers adopted policies restricting covered entities' use of contract pharmacies to dispense 340B priced drugs based on concerns that the arrangements create opportunities for abuse of the Section 340B program and impose significant costs on drug manufacturers. In response, several states, including Mississippi, enacted laws regulating drug manufacturers' treatment of contract pharmacies. Mississippi's H.B. 728 prohibits drug manufacturers from "deny[ing], restrict[ing], prohibit[ing], or otherwise interfer[ing] with, either directly or indirectly, the acquisition . . . or delivery of" 340B priced drugs to contract pharmacies. MISS. CODE ANN. § 41–149–7 (2024).

Novartis sued the Attorney General of Mississippi for declaratory and injunctive relief and sought a preliminary injunction against the enforcement of H.B. 728 on grounds that it was preempted by federal law. The district court found that Novartis had not shown a substantial likelihood of success on the merits of its claim and denied the motion for a preliminary injunction. Novartis appealed.

II

We review the denial of a preliminary injunction for abuse of discretion, reviewing underlying legal determinations de novo and factual findings for clear error. *Anibowei v. Morgan*, 70 F.4th 898, 902 (5th Cir. 2023); *AbbVie, Inc. v. Fitch*, 152 F.4th 635, 642 (5th Cir. 2025).

A party seeking a preliminary injunction must establish:

> (1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable injury if the injunction is not issued, (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted, and (4) that the grant of an injunction will not disserve the public interest.

AbbVie, 152 F.4th at 642 (quoting *Jones v. Tex. Dep't of Crim. Just.*, 880 F.3d 756, 759 (5th Cir. 2018)). When the government is a party, factors three and four merge. *Id.*

III

Novartis argues that because H.B. 728 "dramatically expands" the scope of Section 340B, the district court erred in finding that it failed to show a likelihood of success on the merits of its claim that under the Supremacy Clause, H.B. 728 is preempted by federal law.

The Supremacy Clause provides that the laws of the United States "shall be the supreme Law of the Land . . . any Thing in the Constitution or

Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. "Congress may implicitly preempt state law in two ways: field preemption and conflict preemption." *AbbVie*, 152 F.4th at 645. Field preemption occurs when Congress's intent to exclusively occupy a field can be inferred from pervasive federal regulation or a dominant federal interest. *Arizona v. United States*, 567 U.S. 387, 399 (2012); *Janvey v. Democratic Senatorial Campaign Comm., Inc.*, 712 F.3d 185, 200 (5th Cir. 2013). Conflict preemption occurs when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona*, 567 U.S. at 399. In areas traditionally regulated by the states, courts apply a presumption against preemption, requiring a clear and manifest congressional intent to displace state law. *Deanda v. Becerra*, 96 F.4th 750, 761 (5th Cir. 2024).

Novartis first argues that the district erred in applying the presumption against preemption because H.B. 728 does not regulate traditional state police powers. We recently rejected a pre-enforcement preemption challenge to H.B. 728 substantially similar to that of Novartis in *AbbVie*. *AbbVie* explained that H.B. 728 regulates the distribution of drugs to patients and the role of pharmacies in that process—areas of public health and consumer protection traditionally governed by the states. 152 F.4th at 646–47; *see also AbbVie, Inc. v. Murrill*, 166 F.4th 528, 539 (5th Cir. 2026) (applying *AbbVie* to a materially indistinguishable Louisiana law and rejecting the argument that the presumption against preemption did not apply because the Louisiana law regulates public health and consumer protection, areas traditionally within a state's police powers). Because *AbbVie* found that H.B. 728 regulates areas traditionally governed by the states, the presumption against preemption applies, and the district court did not err in applying it.

Novartis next argues that the district erred by finding that H.B. 728 is not field preempted by federal law because Congress intended to occupy

the field of the Section 340B program. *AbbVie* explained that Section 340B is a drug pricing program that regulates costs, eligibility, and compliance, but it does not govern "the distribution of [340B priced] drugs to patients and the role of pharmacies in such distribution." 152 F.4th at 647. Because Congress left those matters unaddressed, they remained subject to state regulation. *Id.* at 646–47. And in any event, because H.B. 728 regulates areas traditionally reserved for the states, the presumption against preemption applies, reinforcing *AbbVie*'s conclusion that Congress did not intend to exclusively occupy the field. *Id.* at 647.

Finally, Novartis argues that the district erred by not finding that H.B. 728 interferes with federal requirements. *AbbVie* found that H.B. 728 "does not compel manufacturers to 'offer' discounted drugs to contract pharmacies in the way that Section 340B compels . . . [manufacturers] to 'offer' these drugs to covered entities." *Id.* at 647. Nor does "H.B. 728's enforcement scheme . . . conflict with Section 340B's enforcement scheme," it noted, because the statutes do not regulate the same subject matter. *Id.* at 647–48. For these reasons, *AbbVie* held, H.B. 728 does not stand as an obstacle to Section 340B's objectives. *Id.*

Novartis seeks to distinguish *AbbVie*, noting that it found insufficient record evidence to show that H.B. 728 permits diversion of discounted drugs in violation of Section 340B. Here, Novartis argues that H.B. 728 prohibits drug manufacturers from maintaining contract pharmacy policies that are permitted under federal law, which in turn forces them to extend discounts beyond what Section 340B requires. But *AbbVie* expressly found that H.B. 728 "does not compel manufacturers to 'offer' discounted drugs to contract pharmacies"; it only requires them to allow covered entities to *receive* 340B priced drugs through the pharmacies they use to distribute drugs. 152 F.4th at 647 (citation modified). Because *AbbVie* rejected the same theories that Novartis advances here, it controls, and we are bound by that

holding under our rule of orderliness. *See Murrill*, 166 F.4th at 539 (finding that "[*AbbVie*] controls" the preemption analysis for a materially identical Louisiana statute); *Jacobs v. Nat'l Drug Intel. Ctr.,* 548 F.3d 375, 378 (5th Cir. 2008) ("It is a well-settled Fifth Circuit rule of orderliness that one panel of our court may not overturn another panel's decision, absent an intervening change in the law, such as by a statutory amendment, or the Supreme Court, or our *en banc* court.").

Because Novartis failed to show a likelihood of success on the merits of its preemption claim, the district court did not abuse its discretion by denying a preliminary injunction. *See AbbVie*, 152 F.4th at 648.

AFFIRMED.