

**IN THE UNITED STATES COURT OF APPEALS  
FOR THE FIFTH CIRCUIT**

\_\_\_\_\_  
No. 14-10923  
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United States Court of Appeals  
Fifth Circuit

**FILED**

September 30, 2015

Lyle W. Cayce  
Clerk

NIGEN BIOTECH, L.L.C., a Utah limited liability company,

Plaintiff - Appellant

v.

KEN PAXTON, in his official capacity as the Attorney General for the State  
of Texas,

Defendant - Appellee

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Appeal from the United States District Court  
for the Northern District of Texas  
\_\_\_\_\_

Before DAVIS, JONES, and CLEMENT, Circuit Judges.

EDITH H. JONES, Circuit Judge:

A manufacturer and distributor of over-the-counter dietary supplements, Isodrene and The HCG Solution, appeals the district court's order dismissing its constitutional and state law claims against the Attorney General of the State of Texas on the sole basis of state sovereign immunity. We conclude that it is at least partially correct that NiGen's claims are not barred from federal jurisdiction on the basis of *Ex parte Young*; federal jurisdiction plainly exists over most of the constitutional claims pled; and

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NiGen has standing to sue. Accordingly, we affirm in part, and vacate and remand in part for further proceedings.

### **BACKGROUND**

NiGen makes and sells dietary supplements, two of which contain the “individual amino acid building blocks” of prescription-drug ingredient hCG.<sup>1</sup> The company labels the packages of these products with the term “hCG,” which the Attorney General of the State of Texas (the “AG” or the State) determined was “false, misleading, or deceptive” in violation of the Texas Deceptive Trade Practices Act (“DTPA”) because, among other reasons, “the claim is trying to mimic claims that FDA considers off-label for the prescription drug.” In October 2011, the AG sent letters to this effect to NiGen and its retailers, including CVS, Walgreens, and Wal-Mart, intimating that formal enforcement was on the horizon for both NiGen and the retailers. The retailers pulled the products from their shelves in Texas and other states, allegedly costing NiGen millions of dollars in lost revenue.

NiGen filed suit in December 2011 under 42 U.S.C. § 1983, alleging violations of its rights under the First Amendment, Fourteenth Amendment Due Process and Equal Protection Clauses, the Commerce Clause, and the Supremacy Clause. The company also alleged a state law claim of tortious interference with existing business relations. NiGen sought 1) a declaration that its labeling did not violate federal law and that it was entitled to use “HCG” on its labels; 2) preliminary and permanent injunctive relief; 3) money damages; and 4) costs and attorneys’ fees.

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<sup>1</sup> hCG is an acronym for human chorionic gonadotropin hormone, a protein found in pregnant women that is an ingredient in prescription drugs sold under the brand names Novarel, Ovidrel, and Pregnyl.

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The AG moved for dismissal, alleging both jurisdictional and pleading defects. As for the jurisdictional claims, the AG argued that the plaintiff lacked Article III standing because the only injury to NiGen was the result of third-party action; that the “federal statutory claim” was non-justiciable because NiGen asked for a declaration that its labeling did not violate FDA law, though the AG was never attempting to enforce federal law; and that state sovereign immunity barred the money damages and state law claims. The AG alternatively averred that NiGen’s claims fail to state a claim as required by Federal Rule of Civil Procedure 12(b)(6). Substantial briefing and pretrial motions preceded the submission of these motions to the court in July 2012.

For reasons not apparent in the record, the district court did not rule for almost two years. Then, despite the plethora of jurisdictional issues before it, the court dismissed the entire case as barred by state sovereign immunity. NiGen seasonably appealed.

### STANDARD OF REVIEW

We review the trial court’s jurisdictional determinations *de novo*. *Fontenot v. McCraw*, 777 F.3d 741, 746 (5th Cir. 2015). “The question of whether state defendants are entitled to sovereign immunity is likewise reviewed *de novo*.” *Moore v. La. Bd. of Elementary & Secondary Educ.*, 743 F.3d 959, 962 (5th Cir. 2014); *see also Hale v. King*, 642 F.3d 492, 497 (5th Cir. 2011) (per curiam). We review the court’s rulings on Rule 12(b)(6) motions *de novo* and must determine whether the pleaded facts state plausible claims that are cognizable in law. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 1974 (2007). Federal courts may analyze arguments that question our jurisdiction in any order. In this unusual situation, all of

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the jurisdictional arguments must be addressed for NiGen's suit to proceed in federal court.

## DISCUSSION

The district court concluded that state sovereign immunity barred NiGen's entire suit and therefore pretermitted analysis of the AG's other arguments. The district court cited *Aguilar v. Texas Department of Criminal Justice* for the broad proposition that "a suit against state officials that is in fact a suit against a State is barred regardless of whether it seeks damages or injunctive relief." 160 F.3d 1052, 1053 (5th Cir. 1998) (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 102, 104 S. Ct. 900, 909 (1984)). This is deficient not least because shortly thereafter the opinion acknowledges the availability of *Ex parte Young* suits to enforce federal law.<sup>2</sup> Rather than fully defend the district court's reasoning, the AG resurrects its original arguments against federal jurisdiction and raises new ones.

### A. State Sovereign Immunity

The several states of our union retained those aspects of sovereignty that the people did not explicitly assign to the federal government.<sup>3</sup> Since the judicial article does not "create new and unheard of remedies," *Hans v. Louisiana*, 134 U.S. 1, 12, 10 S. Ct. 504, 506 (1890), the sovereign states cannot be sued without their consent. See *Papasan v. Allain*, 478 U.S. 265, 276, 106 S. Ct. 2932, 2939 (1986). As a result, "Federal courts are without

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<sup>2</sup> Moreover, *Aguilar* itself was filed not against an individual state officer acting in his official capacity, but against the Texas Department of Criminal Justice, a state agency that shares the sovereign immunity of the State of Texas.

<sup>3</sup> *Alden v. Maine*, 527 U.S. 706, 713, 119 S. Ct. 2240, 2246-47 (1999); see also *In re New York*, 256 U.S. 490, 497, 41 S. Ct. 588, 589 (1921) (discussing state sovereign immunity as "the fundamental rule of which the amendment is but an exemplification").

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jurisdiction over suits against a state, a state agency, or a state official in his official capacity unless that state has waived its sovereign immunity or Congress has clearly abrogated it.” *Moore*, 743 F.3d at 963. Texas has not consented by statute, and § 1983 does not abrogate state sovereign immunity. *Quern v. Jordan*, 440 U.S. 332, 340, 99 S. Ct. 1139, 1145 (1979).

“A suit is not ‘against’ a state, however, when it seeks prospective, injunctive relief from a state actor . . . based on an alleged ongoing violation of the federal constitution.” *K.P. v. LeBlanc*, 729 F.3d 427, 439 (5th Cir. 2013). Under the doctrine articulated in *Ex parte Young*,<sup>4</sup> 209 U.S. 123, 28 S. Ct. 441 (1908), a state official attempting to enforce an unconstitutional law “is stripped of his official clothing and becomes a private person subject to suit.” *K.P. v. LeBlanc*, 627 F.3d 115, 124 (5th Cir. 2010). “Suits by private citizens against state officers in their official capacit[ies] are not, therefore, categorically barred.” *Fontenot*, 777 F.3d at 752. NiGen sued the Attorney General in his official capacity, satisfying the first requirement of *Ex parte Young*.

Certain of NiGen’s claims fail, however, to the extent they request retrospective money damages. A claim for money damages “seek[s] to impose a liability which must be paid from public funds in the state treasury.” *Edelman v. Jordan*, 415 U.S. 651, 663, 94 S. Ct. 1347, 1356 (1974). As the AG correctly points out, the Eleventh Amendment bars federal court jurisdiction over such claims.

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<sup>4</sup> Although the doctrine is universally associated with *Ex parte Young*, the central conceit can be traced further back. See, e.g., *United States v. Lee*, 106 U.S. 196, 197, 1 S. Ct. 240, 241 (1882).

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Further, NiGen's state law claim for tortious interference with contract fails to establish federal jurisdiction because the *Ex parte Young* doctrine only reaches alleged violations of *federal law*. *McKinley v. Abbott*, 643 F.3d 403, 406 (5th Cir. 2011); *see also Pennhurst State Sch. & Hosp.*, 465 U.S. at 106, 104 S. Ct. at 911.

A final prerequisite of *Ex parte Young* is that "the relief sought must be declaratory or injunctive in nature and prospective in effect." *Saltz v. Tenn. Dep't of Emp't Sec.*, 976 F.2d 966, 968 (5th Cir. 1992). Notably, in the trial court, the AG did not move to dismiss NiGen's federal claims for declaratory and injunctive relief on the grounds that they failed to request prospective relief. Now, on appeal, the AG argues for the first time that even the injunctive and declaratory claims are ineligible for *Ex parte Young* because the plaintiff does not allege an "ongoing violation of federal law." It is true that a complaint must allege that the defendant *is violating* federal law, not simply that the defendant has done so.<sup>5</sup> *See Green v. Mansour*, 474 U.S. 64, 71-73, 106 S. Ct. 423, 427-29 (1985). The State argues that whatever "smattering of present tense language" is in the complaint does not suffice to allege an ongoing violation of federal law. Assuming *arguendo* that the AG has not waived this argument by failing to raise it in the district court,<sup>6</sup> we are unpersuaded, for the Supreme Court has explained that courts generally conduct a "straightforward inquiry into whether [the] complaint alleges an ongoing

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<sup>5</sup> This requirement is similar but not identical to the Article III minimum for standing to request an injunction, which requires ongoing harm or a threat of imminent harm. *See City of Los Angeles v. Lyons*, 461 U.S. 95, 105, 103 S. Ct. 1660, 1667 (1983).

<sup>6</sup> *See Union Pac. R.R. Co. v. La. Pub. Serv. Comm'n.*, 662 F.3d 336, 342 (5th Cir. 2011) (state did not waive Eleventh Amendment immunity defense by not raising it in the district court, where it defended the suit on the merits).

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violation of federal law.” *Verizon Md., Inc. v. Pub. Serv. Comm’n.*, 535 U.S. 635, 645, 122 S. Ct. 1753, 1761 (2002) (alteration in original). NiGen points to the complaint’s straightforward allegations, of which there are many, that the AG’s continued refusal (now after nearly four years) to justify its threatening letters still inflicts, *inter alia*, an unconstitutional restraint on its commercial speech, punishment without due process, and other constitutional violations. These allegations are sufficient to demonstrate the ongoing nature of the alleged unconstitutional conduct, which a federal court could remedy through prospective relief.

### **B. Federal Question Jurisdiction**

The parties also join issue over this court’s subject matter jurisdiction, yet all of NiGen’s claims except for tortious interference are brought under § 1983, a federal statute, and allegedly arise under the U.S. Constitution. “A suit arises under the law that creates the cause of action.” *Am. Well Works Co. v. Layne & Bowler Co.*, 241 U.S. 257, 260, 36 S. Ct. 585, 586 (1916).

The AG argues that all of the federal claims here are really defenses to its threatened DTPA enforcement action. According to the well-pleaded complaint rule, federal jurisdiction is absent when the federal issue appears in the guise of an anticipated defense. *E.g., New Orleans & Gulf Coast Ry. Co. v. Barrios*, 533 F.3d 321, 328 (5th Cir. 2008). And in an action for declaratory judgment, the inquiry is inverted: Since a declaratory judgment action is inherently anticipatory, the federal issue must form part of the hypothetical well-pleaded complaint that the declaratory judgment defendant would have filed but for the anticipatory action. *See Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671, 70 S. Ct. 876, 879 (1950).

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To the extent that NiGen seeks as its first cause of action a declaration that “its use of the letters ‘HCG’ on its packaging and labeling has not violated any federal law, and that Plaintiff is entitled to use the letters ‘HCG’ on its packaging and labeling for Isodrene and The HCG Solution,” the company’s allegations plainly assert a defense to a not-yet-commenced state enforcement action. Although the question whether NiGen’s product and labelling comport with federal FDA law may become a defense in such an enforcement action, this is hardly a sure thing; the State’s letters principally alleged potential violations of state deceptive trade practices law. This court’s recent decision in *Singh v. Duane Morris LLP*, 538 F.3d 334, 338 (5th Cir. 2008) set out a four-part test, determining that a federal court may exercise jurisdiction over a state law cause of action when: “(1) resolving a federal issue is necessary to the resolution of the state-law claim; (2) the federal issue is actually disputed; (3) the federal issue is substantial; and (4) federal jurisdiction will not disturb the balance of federal and state judicial responsibilities.” The party asserting jurisdiction has the burden to prove all of these elements. NiGen’s stand-alone pleading for declaratory relief plainly does not satisfy the first three tenets on the present state of the record.

The AG more generally contends that all of NiGen’s claims are essentially anticipatory defenses to the threatened enforcement action, hence all are barred. We disagree with this proposition. A number of cases have held that where a plaintiff in NiGen’s position seeks both declaratory and injunctive relief, the *Wycoff* rule<sup>7</sup> does not prevent that plaintiff from

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<sup>7</sup> *Public Service Comm’n. of Utah v. Wycoff Co.*, 344 U.S. 237, 248, 73 S. Ct. 236, 242-43 (1952)(looking to whether federal jurisdiction exists over threatened action, not the defense, in a claim for declaratory relief).



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establishing federal jurisdiction. In *A&R Pipeline Corp. v. Commissioner, State of Oklahoma*, 860 F.2d 1571 (10th Cir. 1988) the court, when faced with an analogous case, sustained federal jurisdiction:

We express no opinion concerning the dicta in *Wycoff* and its progeny because this suit is not based solely on a claim for declaratory judgment but also includes a claim for injunction.

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The district court's jurisdiction to resolve the pipeline's claim for injunction extends to enable the court also to resolve the issues raised by the declaratory judgment action.

We reached a similar conclusion in *Braniff International, Inc. v. Florida Public Service Commission*, 576 F.2d 1100 (5th Cir. 1978). In that case we stated:

We hold that where a party seeks injunctive and declaratory relief based upon the unconstitutionality of a state statute where there are no other concrete impediments to a proper exercise of federal question jurisdiction, the mere fact that the constitutional claims might be raised before a state administrative body charged with enforcement of the statute does not alone deprive the court of jurisdiction.

Regardless of the ultimate merit of NiGen's claims, with the sole exception of the stand-alone declaratory judgment cause of action, there is federal question jurisdiction over the constitutional claims NiGen asserts under § 1983.

### **C. Standing**

The State also challenges NiGen's standing to bring this suit. It is true that "a plaintiff must demonstrate standing separately for each form of relief sought." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 185, 120 S. Ct. 693, 706 (2000). To have standing to sue, the

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plaintiff must demonstrate injury in fact that is fairly traceable to the defendant's conduct and that would be redressed by a favorable judicial decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S. Ct. 2130, 2136 (1992). However, the complaint need only "allege facts from which it reasonably could be inferred," *Warth v. Seldin*, 422 U.S. 490, 504, 95 S. Ct. 2197, 2208 (1975), that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision," *Lujan*, 504 U.S. at 61, 112 S. Ct. at 2137 (internal quotation marks omitted).

The injury-in-fact and traceability requirements are not disputed here. The AG has again taken a different tack on appeal and for the first time challenges redressability. We must address this contention as it goes to federal jurisdiction and cannot be waived, but the fact that it is late-raised reduces the credibility of the AG's argument and disserves the efficiency of the judicial process.

In challenging redressability, the AG cites *Lujan*, which observed that standing to challenge government action "depends considerably upon whether the plaintiff is himself an object of the action (or forgone action) at issue." 504 U.S. at 561, 112 S. Ct. at 2137 (denying standing, in part because the only entities whose actions could redress the plaintiff's alleged injury were nonparties that would not be bound by the judgment). Further, in *Simon v. Eastern Kentucky Welfare Rights Organization*, the plaintiffs complained that an IRS revenue ruling allowed favorable tax treatment for hospitals that treated indigents only in their emergency rooms (instead of also admitting them to inpatient care). 426 U.S. 26, 33, 96 S. Ct. 1917, 1922 (1976). The Supreme Court held that even an order forcing the IRS to change its policy would not necessarily result in the hospitals admitting indigent patients. *Id.*

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at 43, 96 S. Ct. at 1926. The Court held that “unadorned speculation will not suffice to invoke the federal judicial power.” *Id.* at 44, 96 S. Ct. at 1927; *see also Allen v. Wright*, 468 U.S. 737, 758, 104 S. Ct. 3315, 3328 (1984) (IRS’s failure to enforce tax disadvantage against discriminatory private schools would not necessarily redress harm to students in segregated public schools).

These cases, however, turned on remedying conduct that was not initially directed at the plaintiffs themselves. Here, the AG sent threatening letters not only to NiGen’s retailers in Texas but also to the company itself. As NiGen cogently explains, “these letters harmed NiGen directly because they amounted to a preliminary injunction against the lawful sale of NiGen’s products. NiGen’s retailers removed the products from their shelves only as a direct result of receiving the threatening letters from the Attorney General.” NiGen Reply Br. at 17. Further, because “NiGen itself continues to be effectively enjoined from selling its products,” a favorable court decision “would allow NiGen to again sell its products freely in Texas, whether directly, through its prior retailers, through other retailers, etc. It would allow NiGen to repair its damaged relationship with its retailers that has resulted from the Attorney General’s conduct. This is not speculative and is not dependent on the actions of third parties.” *Id.* at 17-18. As the Supreme Court has noted, where a plaintiff’s complaint alleges a continuing violation or the imminence of a future violation, a prayer for injunctive relief satisfies redressability. *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 108, 118 S. Ct. 1003, 1019 (1998).

Other court decisions cited by the Attorney General have found the “chain of forward causation” to be broken for redressability purposes, but they are distinguishable. For example, in *Frank Krasner Enterprises, Ltd. v.*

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*Montgomery County*, the owner of an expo venue refused to grant a lease to a plaintiff gun vendor because of a law withdrawing local subsidies for shows where guns were sold. 401 F.3d 230, 232 (4th Cir. 2005). The Fourth Circuit held that even if the law were enjoined, the non-party owner might still decline to do business with the gun seller. *Id.* at 236. The court emphasized the absence of a case granting standing to a plaintiff that challenged a government's decision not to subsidize a third party. *Id.* at 235-36. Similarly, in *Glanton ex rel. ALCOA Prescription Drug Plan v. AdvancePCS Inc.*, 465 F.3d 1123, 1125 (9th Cir. 2006), the plaintiffs were beneficiaries of a mismanaged ERISA drug plan. But the court held that even if their suit against the manager's misdeeds succeeded, it would not follow that the sponsors of the plan would reduce the price of the plaintiff's benefits; consequently, the court could not redress their alleged injury. *Id.* at 1127. Of a similar nature is *Pritikin v. Department of Energy*, 254 F.3d 791, 799-801 (9th Cir. 2001), in which the plaintiffs sued one federal agency on their claim that it had to fund another, with no guarantee that a favorable judgment would in fact cause the funding to occur.

None of these cases sought, like NiGen's, to lift a yoke of alleged unconstitutional conduct from the plaintiff's own shoulders. None of them involved government enforcement threats against third parties. Were NiGen to succeed here and nullify the threats, the likelihood of NiGen's success in returning its products to store shelves in Texas, given the normal marketplace incentives, is much greater than in these other cases. We make no predictions about the outcome of this case except to acknowledge that if NiGen succeeds in enjoining the AG's conduct, which would require a retraction of the offending

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letters and/or the instigation of procedurally adequate enforcement measures, NiGen could again conduct business as usual.

The district court did not rule on the AG's Rule 12(b)(6) motion for failure to state a claim. For two reasons, we remand this ordinarily legal question to that court. First, nearly four years have passed since the delivery of the AG's letters, and we cannot be certain that the facts concerning this case are the same as they were when suit was filed. Second, the dismissal motion seems to rely on discovery and matters outside the pleadings, suggesting that the entire record must be consulted, which is the province of summary judgment rather than a 12(b)(6) motion. The district court is the better venue for this analysis in the first instance.

### CONCLUSION

For the foregoing reasons, the judgment of the district court is **AFFIRMED** insofar as it dismissed NiGen's claims for money damages, for state law violations, for retrospective relief, and for declaratory relief against a threatened enforcement action; the judgment is **REVERSED** insofar as it dismissed NiGen's constitutional law claims; and the case is **REMANDED** for further proceedings.