UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff-Appellee,

V.

PHILIP J. WEISER, in his official capacity as Attorney General of the State of Colorado; PATRICIA A. EVACKO, ERIC FRAZIER, RYAN LEYLAND, JAYANT PATEL, AVANI SONI, KRISTEN WOLF, and ALEXANDRA ZUCCARELLI, in their official capacities as members of the Colorado State Board of Pharmacy,

Defendants-Appellants.

On Appeal from the United States District Court for the District of Colorado No. 1:23-cv-2584-DDD-JPO The Honorable Daniel D. Domenico

BRIEF FOR PLAINTIFF-APPELLEE

ORAL ARGUMENT NOT REQUESTED

ALEXANDRA I. RUSSELL KIRKLAND & ELLIS LLP 1301 Pennsylvania Avenue NW Washington, DC 20004 (202) 389-5000 JAY P. LEFKOWITZ

Counsel of Record

KIRKLAND & ELLIS LLP

601 Lexington Avenue

New York, NY 10022

(212) 446-4970

COLE CARTER KIRKLAND & ELLIS LLP 333 West Wolf Point Plaza Chicago, IL 60654 (312) 862-1951

Counsel for Plaintiff-Appellee

May 1, 2024

CORPORATE DISCLOSURE STATEMENT

Teva Pharmaceuticals USA, Inc. is an indirect, wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. through these parent companies: Teva Holdco US, Inc.; Orvet UK; Teva UK Holdco 1 Limited; Teva UK Holdco 2 Limited; Teva UK Holdco 3 Limited; Teva Finance Holding B.V.; Teva Pharmaceuticals Finance Netherlands B.V.; Teva Pharmaceuticals Europe B.V.; Teva Pharmaceuticals Curacao N.V.; IVAX International B.V.; Teva Pharma B.V.; TEVA Pharmaceutical Works Private Limited Company; Teva Holdings GK; Teva Pharma S.L.U.; Pharma de Espana, Inc.; Norton Healthcare Limited; Teva UK Holdings Limited; Teva Pharma Holdings Limited; LBC International Corp.; Laboratorio Chile, S.A.; Ivax Holdings C.I.; IVAX LLC; and LabChile Investment Corp. Teva Pharmaceutical Industries Ltd. is the only publicly traded parent company of Teva Pharmaceuticals USA, Inc. and no other publicly traded company owns more than ten percent of its stock.

TABLE OF CONTENTS

CORPORATE DISCLOSURE STATEMENT 1
TABLE OF AUTHORITIESii
STATEMENT OF RELATED CASES
INTRODUCTION
STATEMENT OF THE ISSUES
STATEMENT OF THE CASE
A. Teva Sells Life-Saving Epinephrine Auto-Injectors at Competitive Prices. 4
B. Colorado Enacts the Epinephrine Auto-Injector Affordability Program
C. The District Court Denies the State Officials' Motion to Dismiss.
SUMMARY OF ARGUMENT
ARGUMENT11
I. THE ELEVENTH AMENDMENT DOES NOT BAR TEVA'S SUIT FOR PROSPECTIVE INJUNCTIVE RELIEF
II. TAKINGS CLAIMS ARE SUBJECT TO THE SAME EQUITABLE PRINCIPLES AS ANY OTHER CLAIMS
CONCLUSION
CERTIFICATE OF COMPLIANCE
CERTIFICATE OF SERVICE

TABLE OF AUTHORITIES

	Page(s)
Cases	
Boyce v. Gundy, 3 Pet. 210 (1830)	19
Cherokee Nation v. S. Kan. Ry. Co., 135 U.S. 641 (1890)	21
Collins v. Daniels, 916 F.3d 1302 (10th Cir. 2019)	13
Culinary Studios, Inc. v. Newsom, 517 F.Supp.3d 1042 (E.D. Cal. 2021)	16
Di Giovanni v. Camden Fire Ins. Ass'n, 296 U.S. 64 (1935)	20, 25
E. Enters. v. Apfel, 542 U.S. 498 (1998)	20, 21
Edelman v. Jordan, 415 U.S. 651 (1974)	9
EEE Minerals, LLC v. North Dakota, 81 F.4th 809 (8th Cir. 2023)	14, 15
Equitable Life Assur. Soc. of U.S. v. Wert, 102 F.2d 10 (8th Cir. 1939)	18
Exotic Smoke & Vape v. Cox, 2022 WL 2316323 (D. Utah June 28, 2022)	24
Farhoud v. Brown, 2022 WL 326092 (D. Or. Feb. 3, 2022)	24
Gordon v. Norton, 322 F.3d 1213 (10th Cir. 2003)	22, 23
Greystone Constr., Inc. v. Nat'l Fire & Marine Ins. Co., 661 F.3d 1272 (10th Cir. 2011)	17

Heideman v. S. Salt Lake City, 348 F.3d 1182 (10th Cir. 2003)	9
Hendrickson v. AFSCME Council 18, 992 F.3d 950 (10th Cir. 2021)	8, 9
Knick v. Twp. of Scott, 588 U.S. 180 (2019)	passim
Laborers' Int'l Union of N. Am., Local 860 v. Neff, 29 F.4th 325 (6th Cir. 2022)	13, 15, 16
Ladd v. Marchbanks, 971 F.3d 574 (6th Cir. 2020)	12
Long v. Area Manager, Bureau of Reclamation, 236 F.3d 910 (8th Cir. 2001)	15, 16
Los Molinos Mut. Water Co. v. Ekdahl, 2023 WL 6386898 (E.D. Cal. Sept. 29, 2023)	16
Pakdel v. City & Cnty. of San Francisco, 636 F. Supp. 3d 1065 (N.D. Cal. 2022)	24
Pharm. Rsch. & Mfrs. of Am. v. Willaims, 525 F. Supp. 3d 946 (D. Minn. 2021)	18
Pharm. Rsch. & Mfrs. of Am. v. Williams, 64 F.4th 932 (8th Cir. 2023)	passim
Rife v. Okla. Dep't of Pub. Safety, 854 F.3d 637 (10th Cir. 2017)	16
Tarrant Reg'l Water Dist. v. Sevenoaks, 545 F.3d 906 (10th Cir. 2008)	11
Terrace v. Thompson, 263 U.S. 197 (1923)	19, 20, 24
United States v. Union Pac. Ry. Co., 160 U.S. 1 (1895)	19

Va. Hosp. & Healthcare Ass'n v. Roberts, 671 F. Supp. 3d 633 (E.D. Va. 2023)	15, 24
Verizon Md., Inc. v. Pub. Serv. Comm'n of Md., 535 U.S. 635 (2002)	13, 14
Williams v. Utah Dep't of Corrs., 929 F.3d 1209 (10th Cir. 2019)11	1, 12, 23
Ex parte Young, 209 U.S. 123 (1908)	passim
Statutes	
Colo. Rev. Stat. § 6-1-103	7
Colo. Rev. Stat. § 6-1-113	7
Other Authorities	
11A Charles Alan Wright et al., Federal Practice and Procedure § 2944 (3d ed. 2013)), 17, 20
HB 23-1002, 74th Gen. Assemb., Reg. Sess. (Colo. 2023)	5, 6, 7
U.S. Const. amend. V.	passim
U.S. Const. amend. XI	passim

STATEMENT OF RELATED CASES

There are no related district court or appellate cases.

INTRODUCTION

This interlocutory appeal arises from a suit by Teva Pharmaceuticals USA, Inc. ("Teva") that seeks to enjoin the Attorney General of Colorado and the members of the state Pharmacy Board (the "State Officials") from enforcing the requirements of Colorado's epinephrine auto-injector affordability program, which went into effect on January 1, 2024. Under the program, any time a participating uninsured Coloradan buys one of Teva's generic auto-injectors from a Colorado pharmacy, Teva must send the pharmacy a *free* replacement. Teva's only alternative is to reimburse the pharmacy the full price it paid for the auto-injector—an amount that will almost always be *more* than what Teva could make selling the product to a wholesaler. In other words, Teva can either give its product away for free or make a cash payment that equals or exceeds the product's market value to Teva.

The district court has already determined that the affordability program will take Teva's auto-injectors without compensation, in violation of the Takings Clause. That holding is not, however, the subject of this appeal. The only question before this Court is whether the district court properly denied the State Officials' motion to dismiss Teva's suit on the ground that the State Officials are immune from suit under the Eleventh Amendment—an issue that took up just three paragraphs of the district court's twenty-page order.

The State Officials' bid for Eleventh Amendment immunity fails for the straightforward reason given by the district court: the Eleventh Amendment prohibits suits for monetary damages; not suits that, like this one, seek injunctive relief. In their opening brief, the State Officials respond to the district court's ruling with a *non sequitur*. Injunctive relief is not available in this case, they argue, because monetary compensation is the only permissible remedy under the Takings Clause. But even if the State Officials were right that Teva could not ultimately *obtain* injunctive relief, Teva would still be *seeking* injunctive relief. The supposed unavailability of injunctive relief would not somehow transform this case into a suit for damages that the Eleventh Amendment forecloses. Nearly everything in the State Officials' brief is, therefore, beside the point.

The Court thus need not address the State Officials' argument that injunctive relief is categorically unavailable under the Takings Clause. Indeed, the district court has not even resolved that question yet. But if the Court were to address the issue, it should confirm that the same remedial principles that apply to any other claim also apply to takings claims, as the Eighth Circuit recently held in a materially identical case. Courts have long recognized that injunctive relief is warranted when a plaintiff would otherwise be forced to bring a series of repetitive damages actions to stop an ongoing violation of its rights. That is exactly the case here, where the

affordability program authorizes repeated takings of Teva's auto-injectors, with no numerical limit and no end date.

STATEMENT OF THE ISSUES

- 1. Whether, when injunctive relief is unavailable as a matter of law, the Eleventh Amendment prohibits a federal court from hearing a claim seeking such relief.
- 2. Whether injunctive relief is categorically unavailable under the Takings Clause.

STATEMENT OF THE CASE

A. Teva Sells Life-Saving Epinephrine Auto-Injectors at Competitive Prices.

Epinephrine auto-injectors are single-use, spring-loaded syringes that can deliver a dose of the hormone epinephrine (also known as adrenaline) to individuals experiencing anaphylaxis—a potentially fatal allergic reaction that can involve swelling of the throat and tongue, vomiting, and medical shock. FDA first approved the epinephrine auto-injector in 1987. More than thirty years later, in 2018, FDA granted Teva's application to sell the first generic epinephrine auto-injector in the United States.

Teva sells 0.3-milligram and 0.15-milligram epinephrine auto-injectors at a "wholesale acquisition cost" (WAC) of \$300, minus any applicable discounts or price concessions. The WAC for Teva's auto-injectors is approximately half that for

the brand-name products. Teva sells its products to distributors and wholesalers, who then sell the auto-injectors to pharmacies. According to the sales data available to Teva, between June 30, 2022 and June 30, 2023, at least 14,000 of its epinephrine auto-injectors were shipped to pharmacies in Colorado.

B. Colorado Enacts the Epinephrine Auto-Injector Affordability Program.

On June 7, 2023, Governor Jared Polis signed HB 23-1002, a bill "concerning the affordability of epinephrine auto-injectors." The bill began by declaring that "[e]pinephrine auto-injectors are essential because they are the easiest and most efficient way to potentially save the life of an individual exhibiting symptoms of or experiencing anaphylactic shock" and that "[m]any individuals are unable to afford an epinephrine auto-injector because they cannot pay the copayment amount required under their insurance plan or, if they are uninsured, the cost of an epinephrine auto-injector." HB 23-1002 §§ 1(e)–(f), 74th Gen. Assemb., Reg. Sess. (Colo. 2023). The bill addressed this affordability problem through two distinct measures. First, the bill provided that "[f]or health coverage plans issued or renewed on or after January 1, 2024, if a carrier provides coverage for prescription epinephrine auto-injectors, the carrier shall cap the total amount that a covered person is required to pay for all covered prescription epinephrine auto-injectors at an amount not to exceed sixty dollars for a two-pack of epinephrine auto-injectors."

§ 2, 10-16-160 (2). Teva has not challenged the constitutional validity of this sixty-dollar cap on copayments.

Second, the bill directed the Colorado Division of Insurance to establish the "affordability program" at issue here by January 1, 2024. All Coloradans who (a) have a valid prescription for epinephrine auto-injectors, (b) are ineligible for Medicaid or Medicare, and (c) do not have private health insurance that covers the auto-injectors are eligible for the program. § 3, 12-280-142 (3). Eligible individuals can fill out an application form created by the Division of Insurance, submit the application and proof of Colorado residence at any pharmacy, and obtain a two-pack of epinephrine auto-injectors for no more than sixty dollars. *Id.*, 12-280-142 (4)—(7). The initial application remains valid for one year, and there are no limits on the number of epinephrine auto-injectors an individual can obtain under the program.

The constitutional problem is what comes next. The pharmacy can pocket the sixty-dollar payment for the auto-injectors and request *full reimbursement* or *free replacements* from the manufacturer. The bill requires all manufacturers of epinephrine auto-injectors sold in Colorado to "develop a process for a pharmacy to submit an electronic claim for reimbursement" by January 1, 2024. *Id.*, 12-280-142 (8)(b). Within thirty days of receiving a reimbursement claim, a manufacturer must either (a) "reimburse the pharmacy in an amount that the pharmacy paid for the number of epinephrine auto-injectors dispensed through the program" or (b) "send"

the pharmacy a replacement supply of epinephrine auto-injectors in an amount equal to the number of epinephrine auto-injectors dispensed through the program." *Id.*, 12-280-142 (8)(c). Any manufacturer who fails to comply with the bill is subject to "a fine of ten thousand dollars for each month of noncompliance" and "engages in a deceptive trade practice" under the Colorado Consumer Protection Act, which can be enforced by private plaintiffs as well as the state Attorney General, Colo. Rev. Stat. §§ 6-1-103, 6-1-113 (1), and can result in treble damages. *Id.*, 12-280-142(9)(a).

C. The District Court Denies the State Officials' Motion to Dismiss.

Teva filed suit against the State Officials on October 3, 2023, seeking a permanent injunction against the enforcement of the requirement that Teva reimburse or resupply Colorado pharmacies with epinephrine auto-injectors.¹ Teva also moved for a preliminary injunction to stop the reimburse-or-resupply requirement from going into effect on January 1, 2024. The State Officials opposed the motion for a preliminary injunction and then moved to dismiss the case on several grounds, including Eleventh Amendment immunity.

_

¹ Teva originally filed suit against the Attorney General and the Commissioner of the Colorado Division of Insurance. Counsel for the State then represented that the Pharmacy Board, not the Division of Insurance, has the authority to impose the statutory penalties for noncompliance with the requirements of the affordability program. Teva subsequently dismissed the Commissioner of Insurance and named the members of the Pharmacy Board as defendants.

The district court denied the State Officials' motion to dismiss, as well as Teva's motion for a preliminary injunction, on December 27, 2023. The court found that Teva had standing to mount a pre-enforcement challenge, that its claim was ripe, and, as relevant here, that the State Officials were not immune from suit under the Eleventh Amendment. "[T]he Eleventh Amendment shields state officials from monetary claims for takings," the court explained, "[b]ut under the *Ex Parte Young* doctrine, 'a plaintiff may sue individual state officers acting in their official capacities if the complaint alleges an ongoing violation of federal law and the plaintiff seeks only prospective relief." App'x 346 (citing *Hendrickson v. AFSCME Council 18*, 992 F.3d 950, 965 (10th Cir. 2021)). Because "Teva has disclaimed any intent to pursue monetary damages and seeks only prospective injunctive relief," the suit satisfied the *Ex parte Young* exception to Eleventh Amendment immunity. *Id*.

The district court also held that the reimburse-and-resupply requirement would effect a taking of Teva's property, in violation of the Takings Clause. The court nonetheless denied Teva's motion for a preliminary injunction. The court acknowledged that "[t]he possible redundancy and inefficiency of future suits for monetary relief may eventually require injunctive relief" on a permanent basis. App'x 354. But "[p]reliminary relief," the court observed, "is not appropriate unless the harm 'during the time it will take to litigate the case' would make it 'impossible to ... restore the status quo ante in the event they prevail." App'x 353 (quoting

Heideman v. S. Salt Lake City, 348 F.3d 1182, 1189 (10th Cir. 2003)). Preliminary relief was thus not warranted, in the district court's view, because "[a]ny takings claims that accrue between now and the final resolution of the suit can be compensated for with a finite set of, or possibly even a single, lawsuit." App'x 354.

SUMMARY OF ARGUMENT

The Eleventh Amendment issue presented by this case is straightforward. The Eleventh Amendment recognizes the sovereign immunity of states from suits "seeking to impose a liability which must be paid from public funds." Edelman v. Jordan, 415 U.S. 651, 663 (1974). All agree that Teva, the plaintiff in this case, is not seeking to impose any monetary liability on the State of Colorado. Instead, Teva requests an injunction barring the State Officials from enforcing a statute that authorizes repeated takings of Teva's epinephrine auto-injectors without compensation. Teva's suit thus satisfies the Ex parte Young exception to Eleventh Amendment immunity, which permits a plaintiff to "sue individual state officers acting in their official capacities if the complaint alleges an ongoing violation of federal law and the plaintiff seeks only prospective relief." Hendrickson, 992 F.3d at 965. In other words, there is no Eleventh Amendment problem here because Teva is seeking prospective injunctive relief, not monetary damages. It is as simple as that.

The State Officials insist that *Ex parte Young* cannot apply here because injunctive relief is, according to the State Officials, *never* available under the Takings Clause. The exclusive remedy for a taking, the State Officials argue, is fair compensation for the property taken. But that dispute—which the district court has not even resolved yet—is irrelevant to the immunity question. Under *Ex parte Young*, what matters is whether "the plaintiff *seeks* only prospective relief." *Id.* (emphasis added). Here, the answer is indisputably yes. If injunctive relief is categorically unavailable for takings claims, as the State Officials contend, then Teva's suit will fail on the merits. But it will remain the case that Teva "seeks" injunctive relief, not monetary damages, and thus that the suit can be adjudicated in federal court.

In any event, the State Officials are wrong that takings claims are somehow exempt from the standard rules of equity. As the Eighth Circuit recently explained in a materially identical case, courts have long held that "equitable relief will be deemed appropriate" where "effective legal relief can be secured only by a multiplicity of actions, as, for example, when the injury is of a continuing nature." *Pharm. Rsch. & Mfrs. of Am. v. Williams*, 64 F.4th 932, 943 (8th Cir. 2023) ("*PhRMA*") (quoting 11A Charles Alan Wright et al., *Federal Practice and Procedure* § 2944 (3d ed. 2013)). Teva should not be forced to bring an endless series of damages actions to obtain compensation for each auto-injector

commandeered by the State. A court can, instead, simply enjoin the State Officials from enforcing the statute in question—which the district court has already held violates the Takings Clause.

ARGUMENT

I. THE ELEVENTH AMENDMENT DOES NOT BAR TEVA'S SUIT FOR PROSPECTIVE INJUNCTIVE RELIEF.

There should be no dispute that Teva's suit against the State Officials does not implicate the Eleventh Amendment. "The Eleventh Amendment has been interpreted to bar suits against states and state agencies for money damages in federal court." Tarrant Reg'l Water Dist. v. Sevenoaks, 545 F.3d 906, 911 (10th Cir. 2008) (emphasis added). This is, all agree, not a suit "for money damages." Id. And under Ex parte Young, 209 U.S. 123 (1908), "Eleventh Amendment immunity does not extend to a state official sued in his official capacity when the plaintiff seeks only prospective, injunctive relief." Id. (emphasis added). Here, all agree, Teva has sued the State Officials in their official capacities, and the only relief it requests is an injunction barring future enforcement of the affordability program's reimburse-or-resupply requirement. The district court thus had little trouble concluding that the Eleventh Amendment does not shield the State Officials from suit.

The State Officials suggest that the distinction between suits for money damages and suits for prospective relief is immaterial in takings cases because, in *Williams v. Utah Department of Corrections*, this Court joined several other circuits

in holding that "a claim under the Fifth Amendment Takings Clause is barred by Eleventh Amendment immunity ... as long as a remedy is available in state court." 928 F.3d 1209, 1213 (10th Cir. 2019). But Williams actually confirms that the distinction between claims for damages and claims for prospective relief is just as important in takings cases as in any other kind of litigation. When Williams and the other appellate decisions it cited held that the Eleventh Amendment barred takings claims, they were addressing claims for compensation. Indeed, Williams took care to separately address the plaintiff's argument that one of his claims qualified for the Ex parte Young exception because it sought "prospective injunctive relief" against a state official. Id. at 1214. Williams did not dismiss that argument on the ground that the Ex parte Young exception does not apply to takings claims, as the State Officials insist. Instead, the Williams court carefully reviewed the plaintiff's complaint and determined that, in fact, he "did not name any [state] official to be enjoined from a future violation of his federal rights." *Id.* at 1215.

The Eighth Circuit recently confirmed in *PhRMA* that the *Ex parte Young* doctrine applies to takings cases. Because the plaintiff "specifically requested declaratory and injunctive relief" against "ongoing" takings, 64 F.4th at 950, and did not seek "compensation for the damage ... *already caused*," *id.* (quoting *Ladd v. Marchbanks*, 971 F.3d 574, 581 (6th Cir. 2020)), the Eighth Circuit held that "the *Ex Parte Young* exception is applicable, and sovereign immunity does not bar PhRMA's

suit." *Id.* In reaching that conclusion, the Eighth Circuit relied on the reasoning of the Sixth Circuit in *Laborers' International Union of North America, Local 860 v. Neff*, 29 F.4th 325 (6th Cir. 2022), which observed that the defendant's "status as an arm of the State would not prevent us from enjoining [it] from future violations of the Takings Clause." *Id.* at 334 (citing *Ex parte Young*, 209 U.S. 123, 159–60 (1908)).

The State Officials argue that the Sixth and Eighth Circuits erred in concluding that Ex parte Young could apply to takings claims because "injunctive relief is not the way courts vindicate a plaintiff's rights under the Takings Clause." Opening Br. 22. But even if the State Officials were correct that injunctive relief is categorically unavailable in takings cases—which, as explained below, they are not—that would make no difference under the Eleventh Amendment. The Supreme Court has made clear that "[i]n determining whether the doctrine of Ex parte Young avoids an Eleventh Amendment bar to suit, a court need only conduct a straightforward inquiry into whether a complaint alleges an ongoing violation of federal law and seeks relief properly characterized as prospective." Verizon Md., Inc. v. Pub. Serv. Comm'n of Md., 535 U.S. 635, 645 (2002) (emphases added; internal quotation marks omitted); see also Collins v. Daniels, 916 F.3d 1302, 1316 n.10 (10th Cir. 2019). There cannot be any dispute that Teva's complaint "alleges an ongoing violation of federal law"—the repeated taking of its epinephrine autoinjectors under the affordability program—and "seeks relief properly characterized as prospective"—an injunction barring future enforcement of the reimburse-or-resupply requirement. *Verizon*, 535 U.S. at 645.

Whether Teva is ultimately *entitled* to the prospective relief it seeks is a merits question not relevant to the immunity issue. "[T]he inquiry into whether suit lies under Ex parte Young does not include an analysis of the merits of the claim." Id. at 646. It thus makes no difference whether the State Officials are right that the availability of a compensation remedy in state court forecloses the possibility of injunctive relief—which is why the district court did not address that question in its analysis of the Eleventh Amendment issue. Indeed, the district court has not resolved that question at all. The district court stated that "[t]he possible redundancy and inefficiency of future suits for monetary relief may eventually require injunctive relief," App'x 354 (emphasis added), but the court did not need to reach the issue in deciding Teva's motion for a preliminary injunction because, in its view, the concern about endless, redundant claims for compensation "does not apply during the pendency of this suit." *Id*.

The State Officials purport to cite authority holding that the unavailability of injunctive relief forecloses the application of *Ex parte Young*, Opening Br. 24–26, but none of the appellate decisions on which they rely actually reached that conclusion. In *EEE Minerals, LLC v. North Dakota*, 81 F.4th 809 (8th Cir. 2023),

the Eighth Circuit rejected the plaintiff's Ex parte Young argument not because the doctrine does not apply to takings claims, but because her requested injunctive relief was not genuinely prospective and instead "repackage[d] her claim for monetary relief as a request for an injunction that cures past injuries." Id. at 816.2 In Laborers' *International*, as discussed above, the Sixth Circuit actually held that the Ex parte Young exception does apply to takings claims. See supra at 13. The State Officials cite the portion of the opinion concluding that an injunction was unavailable on the merits because the plaintiffs had an "adequate remedy at law" in the form of a suit for compensation, 29 F.4th at 334, but that merits determination had no bearing on the court's Eleventh Amendment analysis. Similarly, in Long v. Area Manager, Bureau of Reclamation, 236 F.3d 910 (8th Cir. 2001), the Eighth Circuit concluded that injunctive relief was unavailable because the plaintiff could seek compensation The court said nothing to suggest the for the alleged taking of his land.³ unavailability of injunctive relief meant the Eleventh Amendment barred the suit.

_

² The district court in *Virginia Hospital & Healthcare Ass'n v. Roberts*, 671 F. Supp. 3d 633 (E.D. Va. 2023) reached a similar decision, holding that "Plaintiffs cannot establish that the *Ex parte Young* exception should apply" because "what they are seeking is really just compensation." *Id.* at 669.

³ On the merits, *Laborers' International* and *Long* are distinguishable from this case because the plaintiffs did not argue injunctions were necessary to avoid an endless series of redundant suits. *See infra* Section II.

Indeed, when the Eighth Circuit concluded that the Eleventh Amendment did *not* bar a takings claim for injunctive relief in *PhRMA*, it did not even cite *Long*.

The State Officials are left with just two out-of-circuit district court decisions that actually held that the Eleventh Amendment barred a takings claim because injunctive relief was not available. *See Los Molinos Mut. Water Co. v. Ekdahl*, 2023 WL 6386898, at *7–8 (E.D. Cal. Sept. 29, 2023); *Culinary Studios, Inc. v. Newsom*, 517 F.Supp.3d 1042, 1064–65 (E.D. Cal. 2021). Those courts conflated the Eleventh Amendment question of what relief the plaintiff *sought* with the merits question of whether the plaintiff could *obtain* that relief.⁴ But the error was inconsequential in both cases, as the result would have been the same: the court would have granted the motion to dismiss, but on the merits rather than Eleventh Amendment grounds.

In sum, there is no need for this Court to decide whether the injunctive relief that Teva requests is available under the Takings Clause. That merits question is irrelevant to the immunity issue, and it would be premature for this Court to consider the availability of injunctive relief given that the district court has not yet decided the matter. *See Rife v. Okla. Dep't of Pub. Safety*, 854 F.3d 637, 653 (10th Cir. 2017) ("[T]he better practice on issues raised [below] but not ruled on by the district court

⁴ The *Los Molinos* court even cited *Laborers' International* as support for its holding, not recognizing that the Sixth Circuit had held that the *Ex parte Young* exception *did* apply to a takings claim, even though injunctive relief was not available on the merits. *See* 2023 WL 6386898, at *8.

is to leave the matter to the district court in the first instance.") (quoting *Greystone Constr., Inc. v. Nat'l Fire & Marine Ins. Co.*, 661 F.3d 1272, 1290 (10th Cir. 2011)). This Court can resolve the Eleventh Amendment issue in the same straightforward fashion as the district court: because Teva seeks prospective injunctive relief, and not money damages, its suit satisfies the doctrine of *Ex parte Young* and is not barred by the Eleventh Amendment.

II. TAKINGS CLAIMS ARE SUBJECT TO THE SAME REMEDIAL PRINCIPLES AS ANY OTHER CLAIMS.

Although there is no need for the Court to address the State Officials' argument that injunctive relief is categorically unavailable for takings claims, if the Court nonetheless reaches the issue, it should hold that the traditional principles governing the availability of equitable remedies apply with full force to takings claims. The rule that equitable relief should be available when "effective legal relief can be secured only by a multiplicity of actions" is a well-established remedial principle, see Charles Alan Wright et al., Federal Practice and Procedure § 2944 (3d ed. 2013), and it justifies an injunction against the continuous taking of Teva's property under threat of punitive action by the State Officials.

The Eighth Circuit recently explained at length—in an opinion that the State Officials do not meaningfully engage with—why injunctive relief should be available in materially identical circumstances. In *PhRMA*, the Eighth Circuit addressed Minnesota's Alec Smith Insulin Affordability Act, which allowed eligible

individuals to obtain insulin from Minnesota pharmacies for relatively small copayments and—like the program at issue here—required manufacturers to either resupply pharmacies "at no charge" or "reimburs[e] the pharmacy in an amount that covers the pharmacy's acquisition cost." 64 F.4th at 937–38. A trade association of manufacturers sued for injunctive and declaratory relief on the ground that the statute took their insulin products without compensation, in violation of the Takings Clause. The district court dismissed the case on the ground that injunctive relief was unavailable because the manufacturers could pursue claims for compensation after surrendering their property. See 525 F. Supp. 3d 946, 951 (D. Minn. 2021). The district court relied heavily, as the State Officials do here, on the Supreme Court's decision in Knick v. Township of Scott, 588 U.S. 180 (2019), which held that a property owner can bring a federal takings claim the moment the government takes his property without compensation. Knick explained that, although a government commits a constitutional violation when it takes property without paying for it, "[a]s long as an adequate provision for obtaining just compensation exists, there is no basis to enjoin the government's action effecting a taking." *Id.* at 201.

The Eighth Circuit reversed, holding that a post-taking suit for compensation was "an inadequate legal remedy because PhRMA's members would be 'bound to litigate a multiplicity of suits' to be compensated." 64 F.4th at 945 (quoting Equitable Life Assur. Soc. of U.S. v. Wert, 102 F.2d 10, 14 (8th Cir. 1939)). The

Eighth Circuit noted that the Supreme Court's general statements about injunctions in *Knick* followed from the traditional rule that equitable relief is unavailable when a plaintiff has an "adequate remedy at law." Knick, 588 U.S. at 200; see also id. at 207 (Thomas, J., concurring) ("Injunctive relief is not available when an adequate remedy exists at law."). Injunctive relief is "ordinarily" unavailable in takings cases because, where the government seizes a single piece of property or enacts a law that deprives the owner of the property's value, an after-the-fact suit for compensation will make the owner whole. *Id.* at 202. "But *Knick* does not hold," the Eighth Circuit explained, "that every state's compensation remedy is adequate in a particular situation." PhRMA, 64 F.4th at 941 (emphasis added). A court must instead consider any unique circumstances of the case before it and determine whether "the legal remedy" of post-taking compensation would be "as complete, practical, and efficient as that which equity could afford." Id. at 942 (quoting Terrace v. Thompson, 263 U.S. 197, 214 (1923)); see also United States v. Union Pac. Ry. Co., 160 U.S. 1, 51 (1895) ("It is not enough that there is a remedy at law. It must be paid and adequate, or in other words, as practical and efficient to the ends of justice and its prompt administration as the remedy in equity.' The circumstances of each case must determine the application of the rule.") (quoting Boyce v. Gundy, 3 Pet. 210, 215 (1830)).

The Eighth Circuit correctly concluded that "the legal remedy of damages is not 'complete, practical, and efficient'" when a statute authorizes an indefinite series of takings. PhRMA, 64 F.4th at 945 (quoting Terrace, 263 U.S. at 214). Because a suit for retrospective damages will be "incapable of compensating the manufacturers for the repetitive, future takings that will occur under the [statute's] requirements," the property owners would be forced to bring "a repetitive succession of inverse condemnation suits," with each new action trying to recover for the takings not covered by the previous suit. Id. The Eighth Circuit noted that courts have long held that "equitable relief will be deemed appropriate" when "effective legal relief can be secured only by a multiplicity of actions, as, for example, when the injury is of a continuing nature." Id. at 943 (quoting Charles Alan Wright et al., Federal Practice and Procedure § 2944 (3d ed. 2013)); see also Di Giovanni v. Camden Fire Ins. Ass'n, 296 U.S. 64, 70 (1935) ("Avoidance of the burden of numerous suits at law between the same or different parties, where the issues are substantially the same, is a recognized ground for equitable relief in the federal courts."). Accordingly, the Eighth Circuit held that the insulin manufacturers could seek an injunction against all future takings authorized by Minnesota's insulin affordability program.

The Eighth Circuit also found support for an injunction in the plurality opinion from *Eastern Enterprises v. Apfel*, 542 U.S. 498 (1998). In *Apfel*, the plaintiffs

sought an injunction against the enforcement of a statute that required former employers to pay annual assessments to the federal government to fund healthcare benefits for retired mineworkers. *See id.* at 514–15. The plaintiffs could have filed a takings claim against the government each year to recover their annual assessments, but the plurality held that an injunction was warranted because "requiring an entity to submit repetitive takings claims 'would entail an utterly pointless set of activities,' as every dollar paid would then entitle that entity to seek compensation for the same amount." *PhRMA*, 64 F.4th at 946 (quoting *Apfel*, 524 U.S. at 521). Similarly, under the affordability programs at issue in *PhRMA* and this case, manufacturers would be forced to reimburse or resupply pharmacies and then "seek[] the same 'dollar-for-dollar' compensation deemed pointless in *Apfel*," unless they can obtain an injunction. *Id.* (citation omitted).

The State Officials do not directly attack the Eighth Circuit's reasoning. Indeed, they hardly discuss the opinion at all. Instead, they obliquely suggest that the Eighth Circuit failed to recognize that "the Takings Clause only requires reasonable, certain, and adequate provision for obtaining compensation" and does not "confer a right to be free from takings." Opening Br. 28 (quoting *Cherokee Nation v. S. Kan. Ry. Co.*, 135 U.S. 641, 659 (1890)). But that is precisely the view of the Takings Clause that *Knick* rejected. *Knick* held that "a property owner has suffered a violation of his Fifth Amendment rights when the government takes his

property without just compensation." 588 U.S. at 185. In other words, the Takings Clause *does* confer a right to be free from uncompensated takings. True, "[g]iven the availability of post-taking compensation," an injunction "barring the government from acting will ordinarily not be appropriate." *Id.* at 202. But "the availability of the [post-taking] procedure" does not "somehow prevent[] the violation from occurring in the first place." *Id.* at 201. "[B]ecause the violation is complete at the time of the taking, pursuit of a remedy in federal court need not await any subsequent state action." *Id.* at 202.

The question, then, is what sort of "remedy" Teva is entitled to. *Id.* Unlike the typical takings plaintiff, Teva is not challenging a one-time seizure of a discrete piece of property or the imposition of a new regulation that eliminates a property's value. Instead, Teva is challenging a statute that authorizes the repeated, continuous seizure of its property without end. Under well-settled remedial principles, Teva should be entitled to equitable relief because, given that it will need to bring a multiplicity of repetitive suits in the absence of an injunction, it lacks an adequate remedy at law.

The State Officials also argue that this Court has rejected the rule that equitable relief is warranted to avoid a multiplicity of suits, but none of the cited authority supports the State Officials' position. In *Gordon v. Norton*, 322 F.3d 1213 (10th Cir. 2003), ranchers in Wyoming sought an injunction against the federal Fish

and Wildlife Service, which had introduced gray wolves that were allegedly killing the plaintiffs' cattle, dogs, and horses. The plaintiffs in *Gordon* did not argue that an injunction was necessary to avoid a multiplicity of suits, so the decision could not possibly have rejected that ground for equitable relief. But *Gordon* is also distinguishable because, in that case, "the lawfulness of the government action [was] not at issue." *Id.* at 1218. The wolves, not the government, were killing the plaintiffs' animals. The government had simply introduced the wolves to the area, which was not itself a taking or unlawful in any other respect, and thus could not have properly been enjoined. Here, by contrast, the State Officials are forcing Teva to hand over its epinephrine auto-injectors without compensation—an act that the district court has already held violates the Fifth Amendment.

Williams is even further afield. Not only did the plaintiff not argue that equitable relief was necessary to avoid a multiplicity of suits; the court did not even hold that an injunction was unwarranted given the plaintiff's allegations. Instead, as discussed above, the Williams court held that the Ex parte Young exception did not apply because the complaint did not actually state a claim for injunctive relief against a state official. See Williams, 928 F.3d at 1215.

The out-of-circuit district court decisions the State Officials cite are similarly irrelevant. *See* Opening Br. 30. None of the plaintiffs in those cases argued for an injunction to avoid a multiplicity of suits. And for good reason—none of those cases

involved continuous, repetitive takings. All involved new regulations that, at the moment of imposition, allegedly took plaintiffs' property without compensation, but authorized no future takings. See Va. Hosp. & Healthcare Ass'n, 671 F.Supp.3d at 641 (challenge to law "den[ying] payment for services already rendered"); Pakdel v. City & Cnty. of San Francisco, 636 F. Supp. 3d 1065, 1073 (N.D. Cal. 2022) (challenge to ordinance "appropriat[ing] a life tenancy from the Plaintiffs to their tenant"); Exotic Smoke & Vape v. Cox, 2022 WL 2316323, at *1 (D. Utah June 28, 2022) (challenge to law prohibiting operation of retail tobacco shop within 1,000 feet of a school); Farhoud v. Brown, 2022 WL 326092, *11 (D. Or. Feb. 3, 2022) (challenge to limitation on right to evict).

The State Officials also argue that Teva would not, in fact, be forced to bring a multiplicity of suits absent an injunction because Teva could wait until the eve of the expiration of the two-year statute of limitations and file a single suit seeking compensation for all auto-injectors it provided during those two years. That may be possible, but it would not be nearly as "complete, practical, and efficient" as simply enjoining Defendants from carrying out an endless series of illegal takings. *PhRMA*, 64 F.4th at 945 (quoting *Terrace*, 263 U.S. at 214). If Teva filed an omnibus suit every two years, it would have to wait many months for its constitutionally required compensation, and Teva would still be forced into repeated, duplicative litigation without end. An injunction is thus still warranted to "[a]void[] ... the burden of

numerous suits at law between the same or different parties, where the issues are substantially the same." *Di Giovanni*, 296 U.S. at 70.

The State Officials end their brief with a policy argument, objecting that the district court's decision to leave open the possibility of injunctive relief "improperly turns the Takings Clause into a weapon to block state policies." Opening Br. 33. But the implications of the district court's ruling are, in fact, quite modest. In the ordinary takings case, in which the government seizes a single piece of property or passes a new regulation that diminishes a piece of property's value, injunctive relief will be unavailable for the reasons given in *Knick*. In such a case, the property owner can obtain complete relief with a single post-taking suit for compensation. The district court simply recognized that, when a government policy authorizes an endless series of illegal takings, injunctive relief may be appropriate on the well-established ground that the remedy at law would require a multiplicity of repetitive suits.

The State of Colorado still has many lawful means at its disposal to increase public access to epinephrine auto-injectors. The State could, for example, impose price controls at the point of sale to Colorado consumers, just as it imposed a limit on insurance copayments. What it cannot do is force Teva to give up its auto-injectors for free, on demand, in perpetuity. An injunction is warranted to stop the

continuous, repeated taking of Teva's property, which cannot otherwise be redressed except through redundant suits for damages.

CONCLUSION

For the foregoing reasons, the Court should affirm the judgment of the district court.

ALEXANDRA I. RUSSELL KIRKLAND & ELLIS LLP 1301 Pennsylvania Avenue NW Washington, DC 20004 (202) 389-5000

COLE CARTER KIRKLAND & ELLIS LLP 333 West Wolf Point Plaza Chicago, IL 60654 (312) 862-1951 Respectfully submitted,

/s/Jay P. Lefkowitz
JAY P. LEFKOWITZ
Counsel of Record
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4970

Counsel for Plaintiff-Appellee

May 1, 2024

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 5,879 words, excluding the parts of the brief

exempted by Fed. R. App. P. 32(f) and 10th Cir. R. 32(B).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6), because it has

been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-

point Times New Roman type.

May 1, 2024

s/Jay P. Lefkowitz
Jay P. Lefkowitz

CERTIFICATE OF DIGITAL SUBMISSION

I hereby certify that with respect to the foregoing:

- (1) all required privacy redactions have been made per 10th Cir. R. 25.5;
- (2) if required to file additional hardcopies, that the ECF submission is an exact copy of those documents;
- (3) the digital submissions have been scanned for viruses with the most recent version of a commercial virus scanning program and according to the program are free from viruses.

s/Jay P. Lefkowitz
Jay P. Lefkowitz

CERTIFICATE OF SERVICE

I hereby certify that on May 1, 2024, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/Jay P. Lefkowitz
Jay P. Lefkowitz