IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff,

v.

PHILIP J. WEISER, in his official capacity as Attorney General of the State of Colorado; PATRICIA A. EVACKO, ERIC FRAZER, 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.

Case No.: 23-cv-2584-DDD-SKC

PLAINTIFF'S OPPOSITION TO THE ATTORNEY GENERAL'S MOTION TO DISMISS (ECF NO. 29, FILED NOVEMBER 15, 2023)

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The Attorney General's motion to dismiss reiterates some of the same procedural objections he lodged against Teva's motion for a preliminary injunction, although the Attorney General drops some of the most obviously baseless objections.[1] Most notably, the Attorney General no longer argues that he is not an appropriate defendant under *Ex parte Young*. He plainly has the authority and willingness to enforce the reimburse-or-resupply requirement as incorporated into the Colorado Consumer Protection Act, consistent with this Court's recent decision in *Bella Health & Wellness v. Weiser*, 2023 WL 6996860, at *4 (D. Colo. Oct. 21, 2023).

The Attorney General's remaining procedural objections fail for the same reasons Teva gave in its reply brief in support of the preliminary injunction. ***First***, injunctive relief is appropriate because "the legal remedy of damages is not 'complete, practical, and efficient'" when a statute authorizes an indefinite series of takings, as the Eighth Circuit recently held in a case concerning a materially identical law. *PhRMA v. Williams*, 64 F.4th 932, 945 (8th Cir. 2023) (quoting *Terrace v. Thompson*, 263 U.S. 197, 214 (1923)). ***Second***, the Eleventh Amendment is no barrier to a suit seeking prospective injunctive relief. ***Third***, Teva has standing to mount a pre-enforcement challenge because there is a near certainty that at least one

[1] The other defendants in this suit, the members of the Colorado Pharmacy Board, have joined the Attorney General's motion in full. *See* Dkt. No. 35.

of the thousands of auto-injectors Teva ships to Colorado each year will be purchased by a participant in the affordability program.

The Attorney General also defends the constitutional merits of the reimburse-or-resupply requirement, which he declined to do in opposing Teva's motion for preliminary injunction. But the Attorney General's invocation of the "police power" cannot save the reimburse-or-resupply requirement, which is clearly a taking "for public use," not an instance of the government seizing or destroying property that represents a threat to the public's health or safety.

I. INJUNCTIVE RELIEF IS WARRANTED BECAUSE TEVA LACKS AN ADEQUATE REMEDY AT LAW.

The Attorney General argues that the injunctive relief Teva requests is unavailable because Teva can pursue claims for just compensation in Colorado state court for any takings of its property under the affordability program.[2] The Attorney General relies on the Supreme Court's decision in *Knick v. Twp. of Scott*, 139 S. Ct. 2162 (2019), which held that a property owner can bring a federal takings claim the

[2] Strangely, the Attorney General frames his argument against injunctive relief as a matter of Eleventh Amendment immunity. But, as the Attorney General himself recognizes, Eleventh Amendment immunity applies when a suit would "impose a liability which must be paid from public funds," which Teva's request for prospective injunctive relief would not. Dkt. No. 29, The Attorney General's Motion to Dismiss ("Mot.") 5 (quoting *Edelman v. Jordan*, 415 U.S. 651, 663 (1974)). Whether injunctive relief is available is a remedial issue, not a question of immunity from suit.

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 2176.

The Attorney General reads this as a categorical holding that, no matter the circumstances, the availability of a post-taking damages action forecloses injunctive relief. But the Eighth Circuit recently held the exact opposite in a suit to enjoin a materially identical law. The *PhRMA* decision concerned Minnesota's Alec Smith Insulin Affordability Act, which allowed eligible individuals to obtain insulin from Minnesota pharmacies for relatively small co-payments 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 on the ground that injunctive relief was unavailable because the manufacturers could pursue claims for compensation after surrendering their property. *See PhRMA v. Williams*, 525 F. Supp. 3d 946, 951 (D. Minn. 2021). The district court relied heavily on the same portions of *Knick* as the Attorney General.

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 where a plaintiff has an "adequate remedy at law." *Knick*, 139 S. Ct. at 2176; *see also id*. at 2180 (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 2177. "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*, 263 U.S. at 214); *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 "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." *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 Attorney General criticizes *PhRMA* for "grafting a 'no multiplicity of suit' requirement onto" the "straightforward rule from *Knick*" that injunctive relief is never available when a damages action is. Mot. 7. But the Eighth Circuit did not graft anything onto *Knick*; it applied the same traditional principles of equity that *Knick* did, to a context that *Knick* had no reason to consider. The *PhRMA* court was correct to conclude that *Knick* did not overrule traditional principles of equity *sub silentio* and replace them with a categorical rule that the availability of a damages action, no matter how inefficient, forecloses injunctive relief in takings cases.

Notably, the Attorney General does not dispute that courts have long held injunctive relief is warranted to avoid a multiplicity of suits. And, understandably, he drops the argument, which he made in opposition to Teva's motion for a preliminary injunction, that Teva could somehow avoid a multiplicity of suits through joining claims or waiting to file omnibus suits at the close of every statute of limitations period. Because there is no question that traditional rules of equity would require an injunction in these circumstances, it should follow that injunctive relief is necessary and appropriate.

Colorado's epinephrine auto-injector affordability program authorizes repeated, uncompensated takings of Teva's property. Absent an injunction, Teva can only obtain compensation through an endless series of damages actions filed every two years. Such a remedy "would entail an utterly pointless set of activities"

that weigh in favor of injunctive relief. *See PhRMA*, 64 F.4th at 946 (quoting *E. Enters. v. Apfel*, 524 U.S. 498, 521 (1998) (plurality opinion)). Because "the legal remedy of damages is not 'complete, practical, and efficient'" in those circumstances, injunctive relief is appropriate. *Id.* at 945 (quoting *Terrace*, 263 U.S. at 214).

II. THE ELEVENTH AMENDMENT DOES NOT BAR TEVA'S REQUEST FOR INJUNCTIVE RELIEF.

The Attorney General argues that "*if* Teva properly reframes its claim [for prospective injunctive relief] as one for just compensation … Eleventh Amendment sovereign immunity still bars such a claim from being brought against any state official in this Court because it would 'impose a liability which must be paid from public funds.'" Mot. 5 (quoting *Edelman*, 415 U.S. at 663) (emphasis added). The Attorney General's argument is irrelevant because Teva has not, and will not, "reframe[ ] its claim as one for just compensation." *Id*. As Teva has explained, it seeks injunctive relief because after-the-fact suits for just compensation cannot adequately remedy the series of continuous takings authorized by the affordability program. *See supra*, Section I.

The Attorney General also argues in a footnote that *Ex parte Young* does not apply because there is no "ongoing" violation of federal law. Mot. 6 n.2. But plaintiffs may seek injunctive relief under *Ex parte Young* to prevent violations of their constitutional rights from occurring in the first place; they need not risk

sanctions before filing suit. *See Bella Health*, 2023 WL 6996860, at *21 (granting pre-enforcement injunction under *Ex parte Young*); *see also Town of Barnstable v. O'Connor*, 786 F.3d 130, 140 (1st Cir. 2015) ("The *Ex parte Young* doctrine's very existence means that a plaintiff *may* frustrate the efforts of a state policy when those efforts violate *or imminently threaten* to violate the plaintiff's constitutional rights …") (emphasis added); *Summit Med. Assocs., P.C. v. Pryor*, 180 F.3d 1326, 1338 (11th Cir. 1999) ("*Ex parte Young* recognized the very real reason a plaintiff may need a vehicle to challenge the constitutionality of a state law before enforcement is imminent.").

Teva's request for injunctive relief falls squarely within the *Ex parte Young* exception to Eleventh Amendment immunity for "suit[s] against individual state officers acting in their official capacities if the complaint alleges an ongoing violation of federal law"—or, as here, an imminent violation—"and the plaintiff seeks prospective relief." *Williams v. Utah Dep't of Corrs.*, 928 F.3d 1209, 1214 (10th Cir. 2019) (quoting *Muscogee (Creek) Nation v. Pruitt*, 669 F.3d 1159, 1166 (10th Cir. 2012)); *see PhRMA*, 64 F.4th at 948–49 (holding that the *Ex parte Young* exception applied to a materially identical suit). The Attorney General's invocation of Eleventh Amendment immunity, which relies on a supposed request for just compensation that Teva has not made, is meritless.

III. TEVA HAS STANDING AND ITS CLAIM IS RIPE.

Teva has standing to mount a pre-enforcement challenge to the reimburse-or-resupply requirement. "[A] plaintiff satisfies the injury-in-fact requirement where he alleges 'an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder.'" *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014) (quoting *Babbitt v. Farm Workers*, 442 U.S. 289, 298 (1979)). In the absence of the reimburse-or-resupply requirement, Teva obviously would not provide Colorado pharmacies with free replacement auto-injectors or reimburse the pharmacies for the auto-injectors' cost. And there is a "credible threat" of prosecution for noncompliance because the statute authorizes the Pharmacy Board to impose monthly $10,000 fines and authorizes both private plaintiffs and the Attorney General to bring CCPA suits for treble damages.

The Attorney General does not even mention the "credible threat" standard for a pre-enforcement challenge, and instead simply asserts that Teva asks this Court to "make a number of assumptions about the operation of the Affordability Program that have not yet obtained." Mot. 8. But Teva makes only three, eminently reasonable assumptions: (1) some eligible Coloradans will actually make use of the affordability program; (2) one or more of those Coloradans will purchase one of

Teva's auto-injectors; and (3) the pharmacies where those purchases take place will submit requests for reimbursement or replacement.

The Attorney General only really contests the second assumption, disputing that the affordability program "will necessarily impact *Teva's* products." Mot. 9 (emphasis in original). But it is a virtual certainty that, at some point during the life of the affordability program, an eligible Coloradan will purchase one of the thousands of auto-injectors that Teva ships to Colorado each year. Colorado law permits pharmacists, when filling a prescription for a brand-name product, to "substitute an equivalent drug product if … in the pharmacist's professional judgment, the substituted drug product is therapeutically equivalent." Colo. Rev. Stat. Ann. § 12-280-125(1)(a) (West 2021). And according to the FDA's "Orange Book," Teva's auto-injectors are one of only *two* generic epinephrine auto-injectors with an "AB" rating, denoting that they have been determined to be bioequivalent to the brand-name product. *See Approved Drug Products with Therapeutic Equivalents* (43d ed. 2023), p. 3-170. Given the number of Teva auto-injectors shipped to Colorado, state law encouraging the use of generic products, and Teva's position in the generic market, it is nothing short of impossible that no eligible Coloradan will *ever* purchase a Teva auto-injector under the affordability program.

The Attorney General also argues that Teva's claim is not ripe because no taking has yet occurred. *See* Mot. 9. But this simply restates Defendants' standing

argument, and as Teva explained above, it has already suffered an injury-in-fact because it faces a "credible threat" of prosecution for failing to acquiesce in the imminent taking of its property without compensation. For the same reasons that Teva has standing, its pre-enforcement challenge is ripe. *See 303 Creative LLC v. Elenis*, 6 F.4th 1160, 1176 (10th Cir. 2021) (noting that "in pre-enforcement challenges, standing and ripeness often 'boil down to the same question'" (quoting *SBA List*, 573 U.S. at 157 n.5)).[3]

IV. THE REIMBURSE-OR-RESUPPLY REQUIREMENT TAKES TEVA'S PROPERTY FOR PUBLIC USE, IN VIOLATION OF THE TAKINGS CLAUSE.

The Attorney General argues, for the first time, that the reimburse-or-resupply requirement complies with the Takings Clause because it takes property pursuant to the state's "police power." Mot. 10. The principal authority for the Attorney General's argument is the Tenth Circuit's unpublished decision in *Lech v. Jackson*, 791 F. App'x 711, 718 (10th Cir. 2019), which held that police officers had not effected a taking when they damaged the plaintiffs' home while trying to apprehend a criminal suspect. *Id*. at 712.

[3] The Attorney General no longer argues, as he did in opposition to Teva's motion for a preliminary injunction, that "prudential ripeness" considerations and the "finality requirement" for takings claims bar Teva's suit.

The Attorney General fails to mention the key distinction that *Lech* articulated between an exercise of the police power upon private property, which does not require compensation, and a taking through the exercise of eminent domain, which does: the former is not a taking "for public use," and thus does not implicate the Takings Clause. *Id*. at 717 (quoting *Lamm v. Volpe*, 449 F.2d 1202, 1203 (10th Cir. 1971)).[4] As another district court in the Tenth Circuit described the distinction, the question is "whether the governmental action operates to secure a benefit for or to prevent a harm to the public." *Britton v. Keller*, 2020 WL 1889017, at *4 (D.N.M. April 16, 2020) (quoting *Patty v. United States*, 136 Fed. Cl. 211, 214 (2018)). Accordingly, in all of the police-power cases cited by the Attorney General, the invasion or destruction of property was incidental to the government's effort to eliminate a threat to public safety, *see Lech*, 791 F. App'x at 712 (damage to home during arrest); *David v. Midway City*, 2021 WL 6927739, at *7 (D. Utah Dec. 14, 2021) (invasions due to snowplowing), or the property itself threatened public safety

[4] The Fifth Circuit recently rejected *Lech*'s rule that there is no taking when property "damaged or destroyed pursuant to the … police power" as lacking any grounding in "history, tradition, or historical precedent." *Baker v. City of McKinney*, 84 F.4th 378, 383–384 (5th Cir. 2023). The Fifth Circuit instead recognized a "necessity exception to the Takings Clause" in situations where it is "objectively necessary" for the government "to damage or destroy … property in an active emergency to prevent imminent harm to persons." *Id*. at 388. The necessity exception obviously would not apply the reimburse-or-resupply requirement. This Court need not decide between the approaches of *Baker* and *Lech*, however, because the reimburse-or-resupply requirement also does not satisfy *Lech*'s police-power exception.

and was destroyed for that reason, *Carrasco v. City of Udall*, 2022 WL 522959, at *1 (D. Kan. Feb. 22, 2022) (removal of trees interfering with electric lines).

Here, the reimburse-or-resupply requirement does not destroy Teva's property because it is dangerous, or in the course of eliminating some other threat to public safety. Instead, the reimburse-or-resupply requirement commandeers Teva's auto-injectors *so that the public can use them.* It clearly authorizes takings "for public use" within the meaning of the Takings Clause. The state cannot commandeer medical products or services, even life-saving ones, and avoid its constitutional obligation to provide compensation simply by invoking the "police power."

CONCLUSION

For the foregoing reasons, Teva respectfully requests that the Court deny the Attorney General's motion to dismiss.

Dated: December 6, 2023

Respectfully submitted,

/s/ Alexandra I. Russell

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STATEMENT OF COMPLIANCE

I hereby certify that the foregoing pleading complies with the type-volume limitation set forth in Judge Domenico's Practice Standard III(A)(1).

/s/ Alexandra I. Russell

CERTIFICATE OF SERVICE

I hereby certify that on December 6, 2023, I caused a copy of the foregoing to be filed through the Court's CM/ECF system.

/s/ Alexandra I. Russell