No. 21-1731

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

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Pharmaceutical Research and Manufacturers of America,

Plaintiff-Appellant,

vs.

Stuart Williams; Stacey Jassey; Mary Phipps; Andrew Behm; James Bialke; Amy Paradis; Rabih Nahas; Samantha Schirmer; Kendra Metz, all in their official capacities as members of the Minnesota Board of Pharmacy,

Defendants-Appellees.

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**ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA, NO. 0:20-CV-01497**

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# BRIEF OF DEFENDANTS-APPELLEES

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## SUMMARY OF CASE AND REQUEST FOR ORAL ARGUMENT

In response to the growing insulin-affordability crisis created by an oligopoly of pharmaceutical manufacturers, the Minnesota legislature required certain insulin manufacturers—based on their Minnesota insulin sales revenue and insulin prices—to provide insulin to eligible Minnesotans in need. Appellant Pharmaceutical Research and Manufacturers of America (PhRMA)—a lobbying organization not subject to the law—sued Appellees, Minnesota Board of Pharmacy members, claiming the law violates the Takings Clause. Rather than the manufacturers seeking compensation for the alleged takings as the Constitution requires, however, PhRMA sought to enjoin this life-saving law.

The district court dismissed. Consistent with Supreme Court precedent, the court held that the availability of just-compensation remedies for insulin manufacturers in state court through Minnesota's adequate procedures foreclosed PhRMA's request for equitable relief. The court did not address Appellees' additional arguments that sovereign immunity and PhRMA's lack of associational standing also required dismissal. Nor did the court reach the merits of PhRMA's claims or requests for relief.

Given the importance of the issues, Appellees agree that 20 minutes of argument time is appropriate.

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## JURISDICTIONAL STATEMENT

The district court lacked jurisdiction to hear PhRMA's claims. The district court determined it did not have subject-matter jurisdiction because PhRMA lacked standing for failing to state a redressable claim. The court did not address the additional jurisdictional issues of sovereign immunity and lack of associational standing. The district court dismissed the case without prejudice, entered final judgment on March 16, 2021, and re-entered the judgment on March 19, 2021. PhRMA appealed on March 30, 2021, under 28 U.S.C. § 1291.

## STATEMENT OF ISSUES

1. When just-compensation remedies are available, may a federal court grant equitable relief invalidating a state law as unconstitutional under the Takings Clause?

   Apposite authorities:

   U.S. Const. amend. V
   *Knick v. Twp. of Scott*, 139 S. Ct. 2162 (2019)
   *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984)
   *Blanchette v. Conn. Gen. Ins. Corps.*, 419 U.S. 102 (1974)
   *Hurley v. Kincaid*, 285 U.S. 95 (1932)

2. Does PhRMA have associational standing to bring a claim that a state law takes insulin manufacturers' property in violation of the Takings Clause?

   Apposite authorities:

   *Hunt v. Wash. State Apple Advertising Comm'n*, 432 U.S. 333 (1977)

3. Does Eleventh Amendment immunity prevent federal courts from enjoining the State's exercise of its sovereign right to take private property for public use?

   Apposite authorities:

   *Idaho v. Coeur d'Alene Tribe of Idaho*, 521 U.S. 261 (1997)
   *Pennhurst State Sch. & Hosp. v. Haldermann*, 465 U.S. 89 (1984)
   *United States v. Jones*, 109 U.S. 513 (1883)

4. Should this Court assume the role of the district court to decide the equitable and constitutional issues raised in PhRMA's summary judgment motion but not reached below?

   Apposite authorities:

   *Cavegn v. Twin City Pipe Trades Pension Plan*,
   223 F.3d 827 (8th Cir. 2000)

## STATEMENT OF THE CASE

More than 30 million Americans, including more than 330,000 Minnesotans, have diabetes. (App.8 ¶ 36.)[1] It is a chronic disease caused by insufficient production of or resistance to insulin, a hormone that lets the body's cells absorb glucose from the blood for energy. (*Id.*) Supplemental insulin is critical to managing diabetes. (App.8-9 ¶¶ 36-39.) Without insulin, cells cannot absorb glucose, leaving too much blood sugar in the bloodstream and causing serious health problems, including organ damage and death. (App.8 ¶ 36; App.55-56, 59, 77.) People with type 1 diabetes will die without insulin, sometimes within days. (App.59, 66.)

### *The Insulin-Affordability Crisis*

Despite insulin's life-sustaining nature, manufacturers have raised the price exponentially in the United States without cause (aside from increasing profits). (App.59.) Scientists developed insulin 100 years ago and sold their patents for $1 to a university that, in turn, allowed manufacturers to produce insulin royalty-free so it could be made widely available. (App.9 ¶ 39; App.41, 78.) Although subject to some refinements, insulin's base formulation has remained generally the same. (App.9 ¶¶ 39-41; App.41.) Yet manufacturers have increased the price of insulin by more than 1,200% since the 1990s; since 2012, the price has doubled, after it tripled in the previous decade. (App.59, 78.) For example, Humalog insulin costs increased

[1] "App." citations refer to the Appellee's appendix.

from $21 per vial in 1999 to $332 in 2019; the price did not change in Canada. (App.59.) While manufacturers could profitably produce insulin for $11 or less per patient per month, it retails around $300 per vial with patients requiring two or more vials a month. (App.66-75, 78.)

These inexplicable price hikes are killing people, while manufacturers are earning $24 billion in annual insulin revenues. Fran Quigley, *Tell Me How It Ends: The Path to Nationalizing the U.S. Pharmaceutical Industry*, 53 U. Mich. J.L. Reform 755, 756-59, 798 (2020). The outrageous insulin prices have caused individuals to ration their insulin and, in some cases—like those of Minnesotans Alec Smith and Jesimya David Scherer-Radcliff—to die. *Id.*; App.59, 77. After aging out of his parents' health insurance, Alec had to ration his insulin because he could not afford the $1,300-a-month refill. (App.42, 59.) Alec died at age 26 from diabetic ketoacidosis, an insulin deficiency. (*Id*.)

Unfortunately, insulin rationing and the resulting adverse health consequences are not uncommon. An estimated 25% of diabetes patients have rationed their insulin due to its cost. (App.63, 78.) Besides causing death and other serious health consequences, insulin rationing may cost Americans billions annually in preventable emergency department visits and hospitalizations. *See* Ashish Jha et al., *Greater Adherence to Diabetes Drugs Is Linked to Less Hospital Use and Could Save Nearly $5 Billion Annually*, 31 Health Aff. 1836, 1842-43 (2012) (*available at*

https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2011.1198) (last visited June 14, 2021.)

The price hikes are possible because there is no fair market for insulin; the insulin market is unique even in comparison to the traditional drug market. (App.38, 59-61, 77-82.) Three manufacturers (and PhRMA members), Eli Lily and Company, Novo Nordisk Inc., and Sanofi, collectively manufacture nearly all insulin sold in the United States. (App.6 ¶13; App.10 ¶ 42; App.60, 66.) They have exploited and protected their oligopoly of the market—and their customers' lifelong need for the product—to charge excessive prices. (App.47, 59-61, 77.) These manufacturers engage in "shadow pricing," in which they raise their competing insulins' prices in lockstep; "patent evergreening," in which they seek repetitive patents on the same drugs for incremental changes to prolong the patent life and extend the monopoly; and "pay-for-delay" schemes in which they pay other competitors to delay market entry. (App.47-48, 60-61); Quigley, *supra*, 53 U. Mich. J.L. Reform 755 at 798-800. They also sue other manufacturers who try to enter the market and states who try to fix the problems the manufacturers created. *See, e.g.*, *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. CV 17-9105, 2020 WL 1151191, (D.N.J. Mar. 9, 2020); *Pharm. Rsch. & Mfrs. of Am. v. Sandoval,* No. 2:17-CV-02315, 2017 WL 5158714 (D. Nev. Nov. 7, 2017); App.60. In the face of these practices, individuals have no

choice but to pay whatever the manufacturers charge because the alternative is death. (App.59-60, 77.)

***The Alec Smith Insulin Affordability Act***

In response to the insulin-affordability crisis and the deaths of Alec and others, the Minnesota Legislature enacted the Alec Smith Insulin Affordability Act. 2020 Minn. Laws ch. 73, § 4, codified as Minn. Stat. § 151.74 (2020). The Act established urgent-need and continuing-safety-net programs that provide lifesaving insulin to Minnesotans who are most at risk of being unable to access affordable insulin. *See* Minn. Stat. § 151.74. Only insulin manufacturers that annually gross $2,000,000 or more from insulin sales in Minnesota are subject to the Act.[2] *Id*., subd. 1(c). Insulin products with a wholesale acquisition cost of $8 or less per milliliter (or other applicable billing unit) are also exempt. *Id*., subd. 1(d).

Under the Act's urgent-need program, Minnesota residents who need insulin and have less than a seven-day supply can apply for free insulin by attesting to their pharmacies that they are eligible under the Act.[3] *Id*., subds. 2, 3. The pharmacist

[2] The three major insulin manufacturers are licensed as manufacturers by the Minnesota Board of Pharmacy. (App.30-32, ¶¶ 2-8.) In exchange for this licensure, the manufacturers agreed to comply with federal and state law, which includes the Act. *See id*., Minn. Stat. § 151.252, subd. 1(d); Minn. R. 6800.1400.

[3] Minnesota residents are ineligible if they are enrolled in medical assistance or MinnesotaCare, have insurance that limits out-of-pocket costs to $75 or less for a 30-day insulin supply, or have received urgent-need insulin under the Act within the previous 12 months (with some exceptions). Minn. Stat. § 151.74, subd. 2.

then dispenses a 30-day supply of the prescribed insulin. *Id*., subd. 3(c). The pharmacy may seek reimbursement from the manufacturer of the dispensed insulin, which must then reimburse the pharmacy's acquisition costs or replace the insulin dispensed. *Id*., subd. 3(d).

Under the continuing-safety-net program, which expires in 2024, insulin manufacturers subject to the Act must have patient-assistance programs available for certain eligible Minnesotans.[4] *Id*., subds. 4, 16. After receiving an application and confirming an individual's eligibility for the program, the manufacturer gives the individual an eligibility statement that is valid for 12 months and renewable if the individual remains eligible. *Id*., subd. 5(a), (b). Or, in certain circumstances, the manufacturer may use its own co-payment assistance program if it better addresses the individual's needs. *Id*., subd. 5(c). The individual submits the eligibility statement to a pharmacy, which orders 90-day supplies of the prescribed insulin from the manufacturer during the eligibility period. *Id*., subd. 6(a), (f). The manufacturer supplies the insulin to the pharmacy at no charge. *Id*., subd. 6(c). The pharmacy may collect up to a $50 co-payment per 90-day supply to cover its costs. *Id*., subd. 6(d), (e).

[4] Minnesotans must have a family income equal to or less than 400% of the federal poverty guidelines and meet other eligibility requirements to qualify. Minn. Stat. § 151.74, subd. 4.

If a manufacturer fails to comply with the Act, the Minnesota Board of Pharmacy may assess administrative penalties. *Id.,* subd. 10. Any penalty the board assesses must be deposited into an insulin-assistance account in the special revenue fund. *Id*.

***Proceedings Below***

PhRMA commenced the current action against members of the Minnesota Board of Pharmacy in their official capacities. (App.7-8, ¶¶ 15-32.) PhRMA alleged that the Act created a per se taking without compensation, as applied to the three insulin manufacturers, in violation of the Takings Clause of the Fifth Amendment. (App.25 ¶¶ 82, 83.) Rather than the manufacturers seeking compensation for the alleged takings, however, PhRMA asked the court to declare provisions of the Act unconstitutional and enjoin their enforcement. (App.28.)

The Board members moved to dismiss. (Doc. 12.)[5] They argued that they were immune from suit, that PhRMA lacked standing, and that PhRMA could not obtain its requested equitable relief for an alleged taking. (Doc. 16, at 16-32.) Less than thirty days after commencing suit and before any discovery occurred, PhRMA moved for summary judgment. (Doc. 14.) It also conditionally moved to supplement its complaint. (Doc. 34.)

[5] "Doc." citations refer to filings in the district court below.

The district court dismissed the action without prejudice and denied as moot PhRMA's motions for summary judgment and to supplement the complaint. (Add.14.) The court held that PhRMA lacked standing to request equitable relief because adequate just-compensation remedies are available to the manufacturers in Minnesota through inverse-condemnation actions. (Add.8-12.) The court did not address the Board's additional sovereign-immunity and associational-standing arguments. (Add.8, n.4.)

## SUMMARY OF ARGUMENT

This Court should affirm dismissal. The district court correctly held PhRMA lacks standing because the law forecloses the equitable relief PhRMA seeks for the alleged takings. When state governments provide just-compensation remedies to property owners who have suffered a taking, equitable relief is unavailable. *Knick v. Twp. of Scott*, 139 S. Ct. 2162, 2176, 2179 (2019). In Minnesota, just-compensation remedies are available through inverse-condemnation proceedings. This Court has determined that Minnesota's just-compensation procedures are adequate.

Rather than the manufacturers seeking compensation for the alleged takings, PhRMA asked the district court to disregard *Knick* and enjoin a life-saving act. PhRMA now asks this Court to side-step *Knick*. PhRMA's arguments about the adequacy of Minnesota's just-compensation procedures are untenable. First, "future

takings"—takings that have not occurred—are not actionable or compensable. (Add.10.) Second, PhRMA failed to plead, and cannot plead, facts showing a real risk of a multiplicity of suits or that equitable relief would be warranted even if the risk were real. Both are required to obtain equitable relief on a multiplicity of suits theory. No inverse-condemnation case has been filed in relation to this Act, much less a multiplicity. Further, because the alleged injury to the manufacturers is fully compensable, the lethal risk of enjoining a life-saving law far outweighs any inconvenience the insulin manufacturers may experience.

The district court also properly rejected PhRMA's attempt to limit *Knick* to injunctive relief. (Add.11-12.) *Knick* foreclosed equitable relief, which includes declaratory relief. *Knick*, 139 S. Ct. at 2176. Regardless, the declaratory judgment PhRMA seeks would be the functional equivalent of an injunction, which would violate the *Knick* rule.

While not addressed by the district court, dismissal was also required on the additional subject-matter jurisdiction grounds the Board members briefed: PhRMA's lack of associational standing and sovereign immunity. PhRMA brought as-applied takings claims, purportedly on behalf of the insulin manufacturers. Because its claims necessarily require substantial participation by the manufacturers, PhRMA lacks associational standing. Further, the Board members are immune from suit in federal court. The narrowly construed *Ex parte Young* immunity exception

does not apply to PhRMA's takings claims because the State is the real, substantial party in interest, and the relief requested would interfere with the State's special sovereignty interest to take private property for public uses.

Finally, this Court lacks jurisdiction to decide the merits of PhRMA's motion for summary judgment in the first instance. *Cavegn v. Twin City Pipe Trades Pension Plan*, 223 F.3d 827, 831 (8th Cir. 2000). If this Court determines the district court had jurisdiction to hear PhRMA's claims, the matter must be remanded to the district court to decide the equitable and constitutional questions it did not address due to its determination that it lacked jurisdiction.

## ARGUMENT

This Court reviews issues of standing and sovereign immunity de novo. *Heglund v. Aitkin Cty.*, 871 F.3d 572, 577 (8th Cir. 2017) (standing); *Lors v. Dean*, 746 F.3d 857, 861 (8th Cir. 2014) (sovereign immunity). PhRMA bears the burden of proving subject-matter jurisdiction, including standing. *Lujan v. Defs. Of Wildlife*, 504 U.S. 555, 561 (1992); *Buckler v. United States*, 919 F.3d 1038, 1044 (8th Cir. 2019). This Court may affirm on any jurisdictional grounds because of its independent obligation to determine whether subject-matter jurisdiction exists. *See Arbaugh v. Y&H Corp.*, 546 U.S. 500, 514 (2006); *Reeder v. Kansas City Bd. of Police Comm'rs*, 733 F.2d 543, 548 (8th Cir. 1984) (stating Court may affirm on any

ground supported by the record); *Lors*, 746 F.3d at 861 (stating sovereign immunity is threshold matter that can be raised at any time).

The district court properly dismissed PhRMA's claims on standing grounds for lack of redressability. Although not decided by the district court, the Court also should affirm dismissal because PhRMA lacks associational standing and because the Board members are immune from suit under the Eleventh Amendment.

As dismissal was proper, the district court correctly denied PhRMA's summary judgment motion as moot. Because the district court did not address PhRMA's summary judgment motion—which presented no jurisdictional issues and involves equitable claims subject to abuse-of-discretion review—it is not properly before this Court. *See Cavegn*, 223 F.3d at 831 (holding Court lacked jurisdiction to decide merits of dispute not reached by' district court). As such, if this Court determines there are no bases to affirm dismissal, it must remand to allow the district court to consider the merits of PhRMA's claims.

## I. THE DISTRICT COURT CORRECTLY DETERMINED THAT PHRMA LACKED STANDING TO PURSUE EQUITABLE RELIEF FOR THE ALLEGED TAKING OF INSULIN MANUFACTURERS' PROPERTY.

To establish standing, a plaintiff must allege that it suffered an injury traceable to the defendant's conduct, and show that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan*, 504 U.S. at 560-61 (cleaned up). PhRMA sought only equitable relief for its takings

claim. The Supreme Court has repeatedly—and recently—held equitable relief for takings claims is foreclosed when just-compensation remedies are available. Minnesota provides just-compensation remedies through adequate procedures, as previously determined by this Court. Because Supreme Court precedent foreclosed the equitable relief PhRMA sought, the district court properly held that it could not redress PhRMA's alleged injury and, therefore, PhRMA lacked standing. (Add.10.)

PhRMA argues equitable relief is available for its takings claim, asking this Court to find Minnesota's just-compensation procedures inadequate for the first time. PhRMA's arguments fail because: (1) just-compensation procedures need not pay for potential future takings to be adequate; (2) unwarranted fears that a multiplicity of suits may occur does not overcome Supreme Court precedent foreclosing equitable relief and, regardless, PhRMA failed to plead facts that would allow relief under a multiplicity-of-suits theory; and (3) historical takings litigation does not support equitable relief here.

PhRMA also argues it is entitled to a declaration the Act is unconstitutional, even if injunctive relief is foreclosed. Again—as the district court correctly determined—PhRMA's arguments fail because the Supreme Court foreclosed equitable relief for takings claims, which includes declaratory relief, and PhRMA's requested declaratory relief is the functional equivalent of an injunction barring enforcement.

### A. Supreme Court Precedent Forecloses Equitable Relief for Alleged Takings.

Under the Takings Clause, private property cannot be taken for public use without just compensation. U.S. Const. amend. V. The clause permits the taking of private property, provided the government gives just compensation. *See id*.; *First Eng. Evangelical Lutheran Church of Glendale v. Los Angeles Cty.*, 482 U.S. 304, 315 (1987). The clause is not designed to limit governmental interference with property rights, but to secure compensation if an interference amounts to a taking. *First Eng.*, 482 U.S. at 315. Any illegality under the Fifth Amendment is confined to the failure to compensate for a taking, which affords no basis for an injunction if compensation may be procured in an action at law. *Hurley v. Kincaid*, 285 U.S. 95, 104 (1932); *Stop the Beach Renourishment, Inc. v. Fla. Dep't of Envtl. Prot.*, 560 U.S. 702, 740-41 (2010) (Kennedy, J., concurring) ("It makes perfect sense that the remedy for a Takings Clause violation is only damages."). The government does not need to provide compensation before a taking occurs to avoid having its action invalidated. *Knick*, 139 S. Ct. at 2167-68; *Hurley*, 285 U.S. at 104.

For these reasons, the Supreme Court has repeatedly held that equitable relief is not available to enjoin a taking of private property for public use when a suit for compensation can be brought against the government after a taking. *See, e.g.*, *Knick*, 139 S. Ct. at 2168, 2167-77, 2179; *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 127-28 (1985); *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1016

(1984); *Blanchette v. Conn. Gen. Ins. Corps.*, 419 U.S. 102, 108, 136, 155 (1974); *Hurley*, 285 U.S. at 104; *see also Story v. Marsh*, 732 F.2d 1375, 1384-85 (8th Cir. 1984) (reversing injunction because landowners had adequate remedy at law). In other words, a court cannot preemptively enjoin a taking unless the property owner has no mechanism to obtain compensation for the taken property.

The Court recently reaffirmed this long-standing principle in *Knick v. Township of Scott*, where it expressly disclaimed the possibility that a plaintiff could seek equitable relief to prevent a taking, rather than seek just compensation. 139 S. Ct. at 2167-68, 2176, 2179. The Court repeatedly assured governments that the federal courts would not invalidate the governments' regulations as unconstitutional under the Takings Clause. *Id*. As the Court stated, "[g]overnments need not fear that our holding will lead federal courts to invalidate their regulations as unconstitutional. As long as just compensation remedies are available—as they have been for nearly 150 years—injunctive relief will be foreclosed." *Id*. at 2179.

### B. Insulin Manufacturers Have a Reasonable, Certain, and Adequate Procedure to Obtain Just Compensation for Any Alleged Takings Under the Act.

Because just-compensation remedies are available to the insulin manufacturers for the takings PhRMA alleged, PhRMA's claims for equitable relief are foreclosed. Minnesota provides just-compensation remedies to property owners through inverse condemnation actions. Add.11; *Am. Fam. Ins. v. City of*

*Minneapolis*, 836 F.3d 918, 923 (8th Cir. 2016); *Nolan & Nolan v. City of Eagan*, 673 N.W.2d 487, 492 (Minn. Ct. App. 2003). In such actions, the court may determine whether a taking occurred and the compensation amount. *Am. Fam. Ins.*, 836 F.3d at 924. Further, Minnesota law provides for interest from the date of taking (currently at 4%) and for attorney's fees, costs, and expenses. Minn. Stat. §§ 117.031, .045, .195; *DeCook v. Rochester Int'l Airport Joint Zoning Bd.*, 811 N.W.2d 610, 613 (Minn. 2012).

This Court has not only determined that Minnesota's just-compensation procedures are adequate; it has never found a state procedure inadequate. *See, e.g.*, *Am. Fam. Ins.*, 836 F.3d at 923-24; *Cormack v. Settle-Beshears*, 474 F.3d 528, 531 (8th Cir. 2007) ("We have been unable to find a case in which this court has declared a state's inverse condemnation procedures to be inadequate."); *Koscielski v. City of Minneapolis*, 435 F.3d 898, 903 (8th Cir. 2006) (holding Minnesota had an adequate procedure to seek just compensation); *Kottschade v. City of Rochester*, 319 F.3d 1038, 1042 (8th Cir. 2003) (same). This Court has also "reject[ed] the contention that litigating a federal takings claim that is based on state government action in state court works an injustice." *Foster v. Minnesota*, 888 F.3d 356, 359 (8th Cir. 2018); *see also San Remo Hotel, L.P. v. City & Cty. of San Francisco*, 545 U.S. 323, 346-47 (2005) (recognizing state courts are competent and experienced in adjudicating federal takings claims).

Minnesota has a procedure for just-compensation remedies, and insulin is compensable. PhRMA did not plead, and does not argue, otherwise. It admits insulin is a fungible commercial good for which the insulin manufacturers can be compensated. (App.11 ¶ 47; Appellant's Br. 1, 21, 65.) If the Act effects a taking, the manufacturers may be compensated for all insulin taken—as well as their litigation expenses—by using the inverse condemnation procedure in state court. Under *Knick* and its predecessors, PhRMA's requested equitable relief is foreclosed.

PhRMA, however, invites this Court to create an exception to *Knick*'s clear language and, for the first time, determine that Minnesota's inverse condemnation proceedings are inadequate. PhRMA "bears the 'heavy burden' of showing that the state remedy is inadequate." *Cormack*, 474 F.3d at 531. PhRMA has failed to meet its burden. Its arguments for its proffered exception to *Knick* are untenable. Minnesota's procedures are adequate; the manufacturers just do not want to use them. This Court should decline PhRMA's invitation and affirm the district court.

### 1. Just-Compensation Procedures Need Not Compensate for Potential Future Takings to be Adequate and Complete.

Despite *Knick*, and this Court's repeated holdings that Minnesota's just-compensation procedures are adequate, PhRMA argues that federal courts should invalidate laws that allegedly effect takings if just-compensation procedures do not compensate for both past takings and separate potential "future takings" in a single action. (Appellant's Br. 25, 28-30, 43.) The district court correctly rejected

PhRMA's argument. A "future taking" does not give rise to a claim under the Takings Clause, and Minnesota's just-compensation provisions are adequate. (Add.10-11.)

PhRMA's argument is unsound because inverse-condemnation procedures by their nature do not compensate for potential future takings. A "future taking" is not a "taking" because no property has been taken. A takings claim does not even accrue until a government takes property without compensation. *Knick*, 139 S. Ct. at 2177. The possibility that property may be taken in the future is not compensable. *Banner v. United States*, 44 Fed. Cl. 568, 576 (1999), *aff'd*, 238 F.3d 1348 (Fed. Cir. 2001). While the manufacturers would prefer to be compensated in advance in case a taking occurs in the future, the Fifth Amendment does not guarantee that just compensation "be meted out in a way more convenient to the landowner than to the sovereign." *United States v. 45.50 Acres of Land*, 634 F.2d 405, 408 n.2 (8th Cir. 1980) (holding district court lacked jurisdiction to award damages for a separate potential future loss within condemnation action, requiring landowner to bring separate action).

If this Court accepts PhRMA's invitation to undo takings jurisprudence, any assertion of a future taking would subject a government to having its regulations or activities enjoined. Such a holding would practically eviscerate *Knick*'s mandates, as regulations are typically continuous and inverse-condemnation actions do not compensate for "future takings." *Knick* made clear that the government does not

need to provide compensation before a taking occurs to avoid having its regulation invalidated. 139 S. Ct. at 2167-68. But PhRMA argues that Minnesota needs to do just that. PhRMA's asserted exception would swallow the rule in *Knick*.

The Supreme Court has rejected equitable relief when continuous takings were alleged. In the *Regional Rail Reorganization Act Cases,* the Court reversed a judgment enjoining enforcement of the Rail Act, which prevented railroads from discontinuing services or abandoning any lines during bankruptcy reorganization proceedings, unless authorized by the government. *Blanchette*, 419 U.S. at 107-08, 116-17. Railroad creditors and shareholders claimed that the law would result in a taking by eroding the estate beyond constitutional limits. *Id*. at 118. And, the government could not assure that a reorganization plan would be implemented within a reasonable time. *Id*. at 123. Still, the Supreme Court reversed the injunction, holding that federal just-compensation proceedings could compensate for any "erosion taking" effected. *Id*. at 136. Because interest on a just-compensation award runs from the date of taking, the Court also rejected arguments that the remedy would come too late. *Id.* at 148 n.35.

Forcing the railroads to continue services at a loss for an indefinite period was an alleged continuous taking that could have resulted in multiple suits, like the taking alleged here. It was not a singular discrete event as PhRMA argued below. The district court had declared the law void as a taking to the extent it would require

"continued operation of rail services at a loss" and enjoined enforcement of the law. *Id*. at 119-20. Regardless, the Supreme Court reversed, holding that the relief awarded was inappropriate because just-compensation procedures were available.

Likewise, the Seventh Circuit reversed an injunction for alleged continuous takings in *Rose Acre Farms, Inc. v. Madigan*, 956 F.2d 670 (7th Cir. 1992). *Rose Acre* involved federal regulations preventing egg producers with suspected salmonella outbreaks from selling their eggs for certain uses until the flock was certified as salmonella free. *Id*. at 671-72. Under the regulation, Rose Acre could not sell whole eggs in cartons and had to kill its flocks to eliminate the salmonella. *Id*. Rose Acre sued the Secretary of Agriculture seeking "an end to interference with its sale of whole eggs." *Id.* at 672. When the case was argued on appeal, the alleged taking had been occurring for more than a year with no end in sight and no certainty of whether Rose Acre would be subject to the restrictions again.[6] As such, the alleged takings were continuous and could not necessarily be decided in one action. Still, the court held that because the Constitution calls for compensation, setting aside the regulation is the wrong remedy. *Id*. at 673. The right remedy was to order payment, not to allow the sale of eggs that may kill people. *Id*. Ultimately, Rose

[6] The first restrictions began in October 1990. This was not a discrete event as the restrictions were placed on its three separate farms—located in different counties—at three separate times and, presumably, Rose Acre would be subject to the regulation again. *Rose Acre Farms, Inc. v. United States*, 559 F.3d 1260, 1264 (Fed. Cir. 2009).

Acre was under the regulation's restrictions for twenty-five months, and did not suffer a compensable taking. *Rose Acre Farms, Inc*, 559 F.3d at 1264, 1283-84.

In another case that recently addressed this issue, a natural gas distributor that had provided gas to a nuclear service site for decades sought an injunction so it could stop supplying gas to the site and abandon its pipeline. *Nat'l Fuel Gas Distrib. Corp. v. N.Y. State Energy Rsch. & Dev. Auth.*, 265 F. Supp. 3d 286, 290 (W.D.N.Y. 2017). The distributor claimed the government refused it access to the pipeline and took its right to possess, use, and dispose of the pipeline. *Id*. at 293. The court interpreted the claims as physical takings claims. *Id.* Like PhRMA, National Fuel argued that monetary relief was unavailable because of continuous takings and that *Eastern Enterprises v. Apfel*, 524 U.S. 498 (1998), permitted equitable relief. *Id.* at 295, n.2. The court rejected both arguments, holding that any taking could be remedied with damages and recognizing that any reliance on *Apfel* was "fundamentally misplaced" because it was a plurality decision. *Id*. at 294-96 & n.2.

Courts post-*Knick* have also denied injunctive relief for alleged repetitive or continuous taking. In *Virginia Hospital & Healthcare Association v. Kimsey*, the plaintiff brought a facial challenge to a law that allegedly would repeatedly take hospitals' and doctors' services and supplies without just compensation. 493 F. Supp. 3d 488, 492 (E.D. Va. 2020). The district court, relying on *Knick*, dismissed the plaintiff's takings claims seeking declaratory and injunctive relief

because just compensation remedies were available. *Id*. at 492-93; *see also Cty. of Butler v. Wolf*, No. 2:20-CV-677, 2020 WL 2769105, at *3-4 (W.D. Pa. May 28, 2020) (denying declaratory relief for alleged continuous taking).

Because Supreme Court cases hold equitable relief is unavailable for takings, PhRMA understandably fails to cite any binding takings authority to support its position that equitable relief is appropriate here. PhRMA relies on the plurality decision in *Eastern Enterprises v. Apfel* and on a First Circuit case, *Asociación De Subscripción Conjunta Del Seguro De Responsabilidad Obligatorio v. Flores Galarza*, 484 F.3d 1 (1st Cir. 2007). Both cases are easily distinguishable.

*Apfel* involved a takings and due process challenge to the Coal Act, which required coal operators to pay premiums into a health-care fund for mineworkers. 524 U.S. at 503. Four justices in the *Apfel* plurality believed that monetary relief was unavailable because Congress could not have contemplated that the Treasury would compensate coal operators a dollar for every dollar paid under the Coal Act. *Id*. at 521. (O'Connor, J., plurality opinion). As such, they determined that equitable relief was permitted when a "challenged statute, rather than burdening real or physical property, requires a direct transfer of funds mandated by the Government," because requiring plaintiffs to bring compensation claims dollar for dollar for what they were required to pay would be pointless. *Id*. (internal quotation omitted). Justice Kennedy concurred that the Coal Act was unconstitutional, but on due

process grounds, and disagreed with the plurality's Takings Clause analysis. *Id*. at 539. Any reliance on *Apfel* is fundamentally misplaced as five justices did not believe the law effected a taking. *See id.* at 539, 554.

*Galarza* involved an interlocutory appeal concerning immunity. 484 F.3d at 6. There, the challenged law and actions involved the transfers of funds between an underwriting association and the Puerto Rico Treasury Secretary. *Id.* at 6-10. The First Circuit applied then-governing *Williamson County Regional Planning Commission v. Hamilton Bank of Johnson City*, 473 U.S. 172 (1985), *overruled by Knick*, 139 S. Ct. 2162, which held that takings claims were not ripe until a state court had denied compensation. The First Circuit held that the claim was ripe because Puerto Rico had no just-compensation procedures for the alleged taking, and because it involved a direct transfer of funds like *Apfel*. *Galarza*, 484 F.3d at 19-20. The court did not decide the claims on their merits. *Id*. at 37.

This case differs from *Apfel* and *Galarza*. Those cases involved determinations that compensation procedures were not available. Also, here, PhRMA alleges the taking of physical property (insulin), not money. (*See* App.25 ¶¶ 82-84.) *Apfel* and *Galarza* addressed only the direct transfer of funds. The *Apfel* plurality specifically exempted statutes that burdened real or physical property from its holding. 524 U.S. at 521.

PhRMA argues that, to the extent manufacturers may choose to reimburse pharmacies for insulin dispensed under the Act's urgent-need program rather than replace the insulin, the takings claim mirrors the issue in *Apfel*. (Appellant's Br. 38-39.) But, even if the manufacturer chooses reimbursement over replacement, it still is not a direct-transfer-of-funds case. The Act here involves insulin, not dollar-for-dollar compensation. (*See* App.25-26 ¶ 84 (alleging reimbursement is for particular dose of insulin dispensed to particular patient)). The Act's purpose is to provide insulin quickly to people who need it to live and cannot afford it. PhRMA cannot plausibly claim that getting insulin to those in need and then having the manufacturers seek compensation for the insulin provided is an "utterly pointless set of activities" like the dollar-for-dollar exchanges in *Apfel* and *Galarza*. Also, unlike the direct-transfer-of-funds cases, the value of the manufacturers' loss here, to the extent there is any, can be determined only through fact-finding after the alleged taking occurs.

There is simply no basis for this Court to create an exception to *Knick* and to determine, for the first time, that Minnesota's inverse-condemnation procedures are inadequate. The alleged taking of insulin is fully compensable and the

manufacturers will not suffer any injustice by bringing claims for compensation in state court. PhRMA's claims for equitable relief are foreclosed.[7]

### 2. PhRMA's Multiplicity-of-Suits Theory is Inapplicable to Takings and Is Not Supported by the Complaint.

PhRMA also argues that, despite *Knick*, equitable relief is available in this case because the insulin manufacturers will have to bring multiple suits to obtain just compensation. (Appellant's Br. at 26-43.) PhRMA bears the burden to show it has no adequate legal remedy due to an actual multiplicity of suits. *See Invs.' Guar. Corp. v. Luikart*, 5 F.2d 793, 795, 797 (8th Cir. 1925) (rejected jurisdiction under a multiplicity-of-suits theory when seven suits were pending); *cf.* Appellant's Br. 39-40 (arguing Board members must show multiple suits will not occur even though no other suits are pending). It failed to meet its burden.

First, PhRMA's multiplicity-of-suits theory does not overcome Supreme Court precedent that equitable relief is foreclosed in takings cases. PhRMA cites no

[7] Although not argued by PhRMA, some amici assert that equitable relief is available when a property owner invokes *Ex parte Young*, 209 U.S. 123 (1908), and makes a facial takings challenge. (*See* Pac. Legal Found. Br. 5.) But, PhRMA has never disputed that this case involves only an as-applied challenge. (Doc. 16, at 25-26; Doc. 27; App.24-26.) The amici's reliance on *Ex parte Young* is also misplaced. That case did not involve a takings claim, and the plaintiffs had no avenue to challenge the alleged constitutionality of the acts without risking severe civil and criminal penalties. *Ex parte Young*, 209 U.S. at 130, 144-145. Further, the cases cited by the amici did not enjoin a taking, they simply allowed matters to proceed against immunity challenges. (*See* Pac. Legal Found. Br. 7 (citing cases)).

takings cases that allowed equitable relief based on a multiplicity-of-suits theory.[8] The cases and treatises PhRMA relies on discuss forum selection between courts of equity and law, prior to the two courts merging in 1938. (Appellant's Br. 25-30.) They do not discuss takings claims. Takings are unique because any illegality under the Fifth Amendment is confined to the failure to compensate for a taking; meaning that equitable relief is foreclosed if compensation is available. *Hurley*, 285 U.S. 95 at 104. That a plaintiff may have to bring separate suits for separate takings does not make compensation unavailable and does not warrant equitable relief.

Second, even if the multiplicity-of-suits theory applies to takings claims, it does not aid PhRMA here. A mere possibility of—or the fear of—successive or repeated suits is not cause for equitable relief; the danger must be real. *Nat'l Priv. Truck Council, Inc. v. Okla. Tax Com'n*, 515 U.S. 582, 591 n.6 (1995); *Equitable Life Assurance Soc'y of U.S. v. Wert*, 102 F.2d 10, 14-15 (8th Cir. 1939); 2 Fred F. Lawrence, *Treatise on the Substantive Law of Equity Jurisprudence*, § 1027 at 1108 (1929); 1 John Norton Pomeroy, *Treatise on Equity Jurisprudence*, § 251¾ at 380-81 (3d ed. 1905). PhRMA's argument that multiple suits will be required for the manufacturers to receive just compensation is hypothetical.

[8] *Apfel* and *Galarza* were both based on the presumption that compensation remedies were unavailable, not on multiplicity-of-suits theories.

PhRMA failed to plead, and cannot plead, any facts establishing the existence or imminence of a multiplicity of suits. (*See generally* App.1-29.) It merely concludes a series of state court actions will be necessary. (App.26 ¶ 85.) The Court need not accept this flawed conclusion as true. *See Glick v. W. Power Sports, Inc.*, 944 F.3d 714, 717 (8th Cir. 2019) (stating courts do not accept conclusory allegations or legal conclusions in a complaint as true). PhRMA cannot state with any certainty that multiple suits will occur when the insulin manufacturers have yet to bring even one. The first inverse-condemnation action will resolve the parties' disputes—as to takings and compensation, if necessary—likely making further actions unnecessary. If the manufacturers bring an action and the "court determines that a taking has occurred, the government retains the whole range of options already available—amending the regulation, withdrawing the invalidated regulation, or exercising eminent domain." *First Eng.*, 482 U.S. at 321.

There is no basis, and it is impractical, to presume that if a state court determines the Act effects a taking, the Board of Pharmacy could or would continue enforcement of the Act, as is, and force multiple inverse-condemnation actions. PhRMA argues the Minnesota legislature's response to a determination the Act effects a taking is far from certain in this case. (Appellant's Br. 40.) But it is exactly this uncertainty that prevents PhRMA from meeting its burden to show that there

will be an actual, rather than merely possible, multiplicity of suits requiring equitable relief.[9]

Finally, even if PhRMA could show a multiplicity of suits is certain, equitable remedies based on a multiplicity of suits are inappropriate where inconveniences to others outweigh advantages to the plaintiff. *See Hale v. Allinson*, 188 U.S. 56, 77-78 (1903); *Wert*, 102 F.2d at 14-15; Lawrence, *supra* § 1024 at 1107. Preventing a multiplicity of suits alone is not necessarily a sufficient reason to provide equitable relief. *Hale*, 188 U.S. at 77; *First State Bank v. Chicago, R.I. & P.R. Co.*, 63 F.2d 585, 591 (8th Cir. 1933). This is especially true when significant public interests are concerned and an injunction may prevent the accomplishment of important government ends. *Hurley*, 285 U.S. at 104 n.3. A court of equity acts cautiously and only upon a clear showing that intervention is necessary to prevent an irreparable injury. *Id*. To determine whether a multiplicity of suits warrants equitable relief, a court must consider: (1) the real convenience to the parties; (2) the adequacy of the plaintiff's legal remedy; (3) the parties' situations; (4) the contested points; and (5) the results if jurisdiction is assumed or denied. *Armour & Co. v. Haugen*, 95 F.2d 196, 198 (8th Cir. 1938).

[9] For example, when a court recently held that a different Minnesota law effected a taking, the legislature amended the law to provide just compensation. *See Hall v. State*, 908 N.W.2d 345, 348 (Minn. 2018) (holding that retaining interest on unclaimed property is a taking); 2019 Minn. Laws 1st Spec. Sess. ch. 7, Art. 10, §§ 14-15(a) (amending law to pay interest on unclaimed property).

These considerations weigh against providing equitable relief. A multiplicity of suits is highly unlikely and, at most, would only require an action every six years given the statute of limitations for takings. *See Foster*, 888 F.3d at 359 (applying six-year limitations period for Fifth Amendment takings claim). Conversely, enjoining the Act would be extremely detrimental to the State and its citizens. The manufacturers have an adequate legal remedy because, if the Act effects a taking, they will be compensated for all their insulin, plus interests, costs, and attorneys' fees under Minnesota's inverse-condemnation procedures. The issues of whether a taking occurred and the just compensation due both can be decided in a state court action. And, the possible results show that PhRMA's requested relief should not be granted. If equitable relief is granted, Minnesotans with diabetes who rely on the Act could suffer serious health consequences or die. Contrarily, if equitable relief is denied, billion-dollar insulin manufacturers may have to bring an inverse-condemnation action once every six years. This Court should reject PhRMA's multiplicity-of-suits theory and affirm dismissal.

#### 3. Takings Litigation History Does Not Support Equitable Relief in this Case.

Because the insulin manufacturers can receive the full value of each vial of insulin allegedly taken (i.e., permanent compensation) when the taking occurs, takings litigation history confirms that equitable relief is foreclosed here, despite PhRMA's contrary contentions. (*See* Appellant's Br. 33-36.) At the United States'

founding, there were no general causes of action to obtain just compensation for land taken. *Knick*, 139 S. Ct. at 2175-76. Landowners who suffered an uncompensated taking of their real property had to bring a common law trespass action (which only allowed for retrospective damages), and an injunction ejecting the government from his property. *Id*. at 2176. They had no way to obtain damages for a permanent taking—that is, compensation for the total value of the taken land. *Id*.

Later, in the 1870s, states began to recognize causes of action for takings, allowing landowners to sue for the value of the land appropriated and receive "permanent damages," i.e., the total value of the land. *Id*.; Robert Brauneis, *The First Constitutional Tort: The Remedial Revolution in Nineteenth-Century State Just Compensation Law*, 52 Vand. L. Rev. 57, 132-33, 141 n.189 (1999). As landowners gained the ability to sue for the appropriated property's full value, courts become reluctant to provide injunctive relief because the owners had an adequate remedy at law. Brauneis, *supra*, at 133-34; *Knick*, 139 S. Ct. at 2176. Today, because the federal and nearly all state governments provide just compensation remedies for takings, equitable relief is generally unavailable. *Knick*, 139 S. Ct. at 2176.

PhRMA relies on this history to argue that because manufacturers cannot get "permanent damages" for future alleged takings under the Act, it is entitled to injunctive relief. But PhRMA's premise is flawed, and it twists the meaning of "permanent damages." The history PhRMA relies on involved real property that the

government could continuously occupy, not personal property. And "permanent damages" refers to the appropriated land's full value (rather than trespass damages), not damages for takings of other distinct parcels or parcels the government had not yet occupied. *See id*.; Brauneis, *supra*, at 133, 141 n.189. Here, PhRMA argues that a manufacturer suffers a distinct, uncompensated per se taking of personal property each time it is forced to provide insulin under the Act. (Appellant's Br. 24.) Unlike land, the government cannot continuously occupy a vial of insulin. The property's full value is immediately taken. As soon as the alleged taking occurs, the manufacturers would be entitled to permanent damages, i.e., the total value of the insulin taken. The history of takings litigation does not support PhRMA's claim for equitable relief.

### C. PhRMA's Requested Declaratory Judgment is Equitable Relief Foreclosed by Supreme Court Precedent.

The district court properly held that *Knick* also foreclosed PhRMA's declaratory relief request, because its effect would be indistinguishable from an injunction. (Add.11-12.) On appeal, PhRMA attempts to circumscribe the holding in *Knick*, and to characterize the declaration it seeks as a "milder" and less "coercive" remedy. (Appellant's Br. 46-47.) But a declaration that the Act effects an unconstitutional taking would functionally enjoin the Board's ability to enforce the Act, and the district court was correct in denying PhRMA's attempted end-run around *Knick*.

Contrary to PhRMA's claim, the Supreme Court did not limit *Knick* to injunctive relief. Instead, it stated that, because "nearly all state governments provide just compensation remedies to property owners who have suffered a taking, *equitable relief* is generally unavailable." 139 S. Ct. at 2176 (emphasis added). "Equitable relief" is a category of remedies that includes declaratory judgments. *See Eccles v. Peoples Bank of Lakewood Vill.*, 333 U.S. 426, 431 (1948) (comparing a declaratory judgment to "other forms of equitable relief"); *Dakotas & W. Minn. Elec. Indus. Health & Welfare Fund v. First Agency, Inc.*, 865 F.3d 1098, 1103 (8th Cir. 2017) (holding declaratory judgment action was an equitable claim).

The Court's expansive language in *Knick*—stating that "equitable relief" is not available for takings claims when there is an adequate remedy in state law—encompasses the declaratory judgment that PhRMA seeks. In a recent post-*Knick* case, a district court rejected the plaintiffs' request for a declaration that a government action constituted an unconstitutional taking. *Bezingue v. Steuben Lakes Reg'l Waste Dist.*, No. 1:19-CV-81, 2020 WL 7338494, at *14 (N.D. Ind. Dec. 14, 2020). Although the plaintiffs sought no injunction, the district court held that "their request is undeniably equitable," and thus likely barred by *Knick*. *Id.* Because insulin manufacturers have an adequate remedy at law, declaratory relief is foreclosed under the plain language of *Knick*.

Further, as the district court correctly stated, the declaration that PhRMA seeks would operate as a de facto injunction. (Add.11.) The Supreme Court has repeatedly held that, where injunctive relief is unavailable or inappropriate, a court cannot issue a declaratory judgment that would have the same effect as an injunction. In *Samuels v. Mackell*, the Court considered whether a federal court could issue declaratory judgment when the *Younger* abstention doctrine disallowed injunctive relief. 401 U.S. 66 (1971). The Court held it could not issue a declaration that a criminal statute was "unconstitutional and void" because it would have "virtually the same practical impact as a formal injunction would." *Id.* at 67, 72. As a result, a declaration would frustrate the same "long-settled principles of equity" as an injunction. *Id.* at 72.

The Court has applied the same principle in numerous cases challenging state tax laws. In such cases, a federal statute bars injunctive relief when "a plain, speedy, and efficient remedy may be had" in a state court. 28 U.S.C. § 1341. Although the statute does not expressly refer to declaratory judgments, on several occasions the Court has recognized that these declarations would merely operate as injunctions and, as a result, are barred. *See Nat'l Priv. Truck Council, Inc.*, 515 U.S. at 591 ("The availability of an adequate legal remedy renders a declaratory judgment unwarranted as well."); *California v. Grace Brethren Church*, 457 U.S. 393, 408 (1982) (holding that there is "little practical difference" between a declaration that a

state tax law is unconstitutional and an injunction enjoining enforcement of that tax law); *Great Lakes Dredge & Dock Co. v. Huffman*, 319 U.S. 293, 299 (1943) ("[C]onsiderations which had led federal courts of equity to refuse to enjoin the collection of state taxes . . . require a like restraint in the use of the declaratory judgment procedure.").

The principle likewise applies when a party seeks declaratory relief for a takings claim. Following *Knick*, several courts have held that a declaratory judgment proclaiming a law violates the Takings Clause cannot issue, because it "would be the functional equivalent" of an injunction. *Baptiste v. Kennealy*, 490 F. Supp. 3d 353, 391 (D. Mass. 2020); *accord HAPCO v. City of Philadelphia*, 482 F. Supp. 3d 337, 358 n.112 (E.D. Pa. 2020) (same); *Cty. of Butler*, 2020 WL 2769105, at *3-4 (holding that declaratory relief "is not the appropriate avenue to pursue" a takings claim).

PhRMA argues that the declaratory judgment would merely clarify the parties' legal rights related to the Act. (Appellant's Br. 47-48.) This argument falls apart upon examination. First, and tellingly, PhRMA does not cite a single takings case supporting this proposition. Some cases PhRMA cites did not involve constitutional challenges at all, but claims arising under federal statutes. *See Dickinson v. Ind. State Election Bd.*, 933 F.2d 497 (7th Cir. 1991) (Voting Rights Act claim); *Ulstein Mar., Ltd. v. United States*, 833 F.2d 1052 (1st Cir. 1987)

(Administrative Procedure Act). Others involved different constitutional provisions, and they carry limited relevance given the unique remedial structure of takings claims. *See Steffel v. Thompson*, 415 U.S. 452 (1974) (First Amendment claim); *Roark v. S. Iron R-1 Sch. Dist.*, 573 F.3d 556 (8th Cir. 2009) (same); *Alsager v. Dist. Ct. of Polk Cty.*, 518 F.2d 1160 (8th Cir. 1975) (vagueness and due process claims); *Caliste v. Cantrell*, 937 F.3d 525 (5th Cir. 2019) (due process claim).

Second, the Court must consider the nature of the declaration that PhRMA seeks. PhRMA requests a declaration that the Act "violate[s] the Takings Clause." (App.28.) But a declaration that the Act violates the Constitution would render it functionally unenforceable, thereby bringing about the same result as an injunction. PhRMA may not bypass *Knick* by seeking a declaratory judgment that the Act is unconstitutional.

The Supreme Court's decision in *Horne v. Department of Agriculture* demonstrates this point. 576 U.S. 350 (2015). In *Horne*, the governing body in charge of enforcing a California raisin law imposed a fine when raisin handlers refused to turn over their raisins. *Id.* at 356. The raisin handlers challenged the fine in court. *Id.* The Court held the handlers could raise a takings-based defense to the fine. *Id*. at 367. After determining the raisin law violated the Takings Clause, the Court held the handlers were not obligated to pay the fine. *Id.* at 370. Likewise, a declaration that the Act violates the Takings Clause in this case would likely strip

the Board of Pharmacy of its ability to enforce the Act. Were the Board to impose a fine under the Act, then the fine could be held unenforceable as it was in *Horne*. Although styled as a declaration, this remedy would have the same effect as enjoining the Act, a remedy foreclosed by *Knick*.

PhRMA implicitly acknowledges the injunctive effect of the declaration it seeks because it admits that the State would have to change its course of action to conform its conduct to the Constitution. (Appellant's Br. 47-48.) A declaration that *requires* the State to change its course of conduct is indistinguishable from an injunction. PhRMA's assertion that a declaration would not "invalidate" the Act, because it would preserve the Act's "binding force," is unsupported and contrary to reality. (*See* Appellant's Br. 48 n.11.)

This Court has held that Minnesota's just compensation provisions are adequate. None of PhRMA's arguments prove otherwise. Because the insulin manufacturers have adequate just compensation remedies for the takings PhRMA alleged, its requested equitable relief is foreclosed by *Knick* and its predecessors. Accordingly, PhRMA lacks standing, and the Court should affirm dismissal.

## II. PHRMA LACKS ASSOCIATIONAL STANDING BECAUSE ITS CLAIM REQUIRES SUBSTANTIAL PARTICIPATION BY THE INDIVIDUAL MANUFACTURERS.

PhRMA is not an insulin manufacturer, and is not directly affected by the Act. For this reason, PhRMA relied on associational standing to assert its claims. (*See* App.6 ¶¶ 13-14.) Because the district court dismissed based on the lack of

redressability, it did not reach the Board members' additional argument that PhRMA lacked associational standing. (Add.8 n.4; Docs. 16, at 19-21; 66, at 9-11.) But this Court may consider PhRMA's lack of associational standing as an independent basis for affirming dismissal. *A.H. ex rel. Hubbard v. Midwest Bus Sales, Inc.*, 823 F.3d 448, 453 (8th Cir. 2016). Even if this Court determines equitable relief is available for the alleged takings, it should nonetheless affirm dismissal on the ground that PhRMA lacks associational standing.

To bring a claim on behalf of its members, an organization must show that its members have standing, the suit it brings is germane to the organization's purpose, and "neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Advertisement Comm'n*, 432 U.S. 333, 343 (1977). As discussed above, the manufacturers lack standing because their alleged injury is not redressable by the equitable relief sought. *See supra* Part I.A-C. But PhRMA also fails the third prong of this test, because its claim stems from the manufacturers' property interests, and their participation is required to provide the factual context needed to resolve that claim.

A takings claim is generally a "poor candidate" for associational standing, for multiple reasons. *Rent Stabilization Ass'n of N.Y.C., Inc. v. Dinkins*, 805 F. Supp. 159, 164 (S.D.N.Y. 1992). First, the remedy for a taking is providing the owner with just compensation, which "necessarily requires the participation of

the individual members" to determine the amount of compensation due. *Wash. Legal Found. v. Legal Found. of Wash.*, 271 F.3d 835, 850 (9th Cir. 2001).[10]

Second, resolving a takings claim is a "difficult, fact-specific inquiry." *Rent Stabilization*, 805 F. Supp. at 164. The Supreme Court has cautioned that it is "particularly important in takings cases to adhere to our admonition that 'the constitutionality of statutes ought not to be decided except in an actual factual setting.'" *Pennell v. City of San Jose*, 485 U.S. 1, 10 (1988) (quoting *Hodel v. Va. Surface Min. & Reclamation Ass'n, Inc.*, 452 U.S. 264, 294-95 (1981)); *see also Mugler v. Kansas*, 123 U.S. 623, 661 (1887) (stating courts "are under a solemn duty, to look at the substance of things, whenever they enter upon the inquiry whether the legislature has transcended the limits of its authority"). Even in a claim based on alleged *per se* physical takings, which PhRMA purports to bring here, consideration of the factual context is a necessary and inevitable requirement. John D. Echeverria, *What is a Physical Taking?*, 54 U.C. Davis L. Rev. 731, 733 (2020)

[10] Associational standing is incompatible with the remedy in this case even if the Court concludes that equitable relief is available for PhRMA's takings claim. The Act was passed in the context of an insulin-affordability crisis caused by the manufacturers that PhRMA represents. As a result, substantial participation of the insulin manufacturers would be required for them to prove that the balance of harms and the public interest favor granting an injunction. *See Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981); *see also Hanover Cty. Unit of the NAACP v. Hanover Cty.*, 461 F. Supp. 3d 280, 289 (E.D. Va. 2020) ("[A]n organization lacks standing to assert claims of injunctive relief on behalf of its members where the fact and extent of the injury that gives rise to the claims for injunctive relief would require individualized proof.").

("[N]otwithstanding the Court's repeated invocation of the *per se* rule, many of the Court's physical takings decisions include language and analysis pointing to a more nuanced, multifactorial approach."). In a takings case, both the claim and the remedy depend on a detailed factual inquiry. Because the resolution of such a case requires the property owner's substantial participation, associational standing is inapposite.

Numerous courts have held that associations lack standing to bring as-applied takings claims, even when seeking only declaratory or injunctive relief. *See Rent Stabilization Ass'n of N.Y.C. v. Dinkins*, 5 F.3d 591, 596-97 (2d Cir. 1993); *Wash. Legal Found*, 271 F.3d at 849-50; *Ga. Cemetery Ass'n, Inc. v. Cox*, 353 F.3d 1319, 1322 (11th Cir. 2003); *Comm. for Reasonable Regul. of Lake Tahoe v. Tahoe Reg'l Plan. Agency*, 365 F. Supp. 2d 1146, 1163-64 (D. Nev. 2005); *Pharm. Care Mgmt. Ass'n v. Gerhart*, No. 4:14-CV-000345, 2015 WL 6164444, at *7-8 (S.D Iowa Feb. 18, 2015), *rev'd on other grounds*, 852 F.3d 722 (8th Cir. 2017). PhRMA fails to provide a compelling reason that this Court should go against the overwhelming weight of caselaw to determine that PhRMA has associational standing to bring an as-applied takings claim.[11] PhRMA's lack of associational standing is an independent basis upon which this court may affirm the district court's dismissal of PhRMA's Complaint.

[11] PhRMA has never disputed that it brought an as-applied, rather than facial, challenge to the Act. (Doc. 16, at 25-26; Doc. 27; App.24-26.)

## III. THE BOARD OF PHARMACY MEMBERS ARE IMMUNE FROM SUIT UNDER THE ELEVENTH AMENDMENT.

In addition to affirming for lack of standing, this Court should affirm the dismissal because the Board members are immune from suit. *Lors v. Dean*, 746 F.3d 857, 861 (8th Cir. 2014) (deciding case on sovereign immunity grounds, although not addressed by district court, because it is a jurisdictional threshold matter that may be raised at any time.) A state is immune from suit in federal court unless the state has consented to be sued or Congress has expressly abrogated the state's immunity. *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 99-100 (1984). This jurisdictional bar applies regardless of the relief sought and extends to state officials when the state is the real, substantial party in interest. *Id*. at 100-01.

A limited exception exists for official-capacity claims seeking prospective injunctive relief from continuing violations of federal law. *Ex parte Young*, 209 U.S. 123, 155-59 (1908); *see Church v. Missouri*, 913 F.3d 736, 747-48 (8th Cir. 2019). The reasoning behind *Ex parte Young*'s so-called "legal fiction" is that an unconstitutional law is "void," so a state official lacks state authority to enforce it. 209 U.S. at 159. As such, "when a federal court commands a state official to do nothing more than refrain from violating federal law, he is not the State for sovereign-immunity purposes." *Church*, 913 F.3d at 747 (quoting *Va. Off. for Prot. & Advoc. v. Stewart*, 563 U.S. 247, 255 (2011)). The exception is narrowly construed and is inapplicable when the state is the real, substantial party in interest,

that is, when the judgment sought would impact the public treasury and domain or interfere with public administration. *Va. Off. for Prot. & Advoc*., 563 U.S. at 255; *Pennhurst*, 465 U.S. at 114, n.25.

Typically, to determine whether the *Ex parte Young* exception applies, "a court need only conduct a 'straightforward inquiry into whether [the] 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) (citation omitted). But courts must police abuses of the exception that threaten to evade sovereign immunity. *Va. Off. for Prot. & Advoc*., 563 U.S. at 256. As such, this Court has recognized that it may question whether the suit and remedy it seeks will implicate special sovereignty interests such that the *Ex parte Young* exception will not apply. *Anderson-Tully Co. v. McDaniel*, 571 F.3d 760, 764 (8th Cir. 2009); *Union Elec. Co. v. Mo. Dep't of Conservation*, 366 F.3d 655, 658 (8th Cir. 2004) (citing *Idaho v. Coeur d'Alene Tribe of Idaho*, 521 U.S. 261, 281 (1997)).

PhRMA asserted that *Ex parte Young* gave the district court jurisdiction to declare the Act violates the Takings Clause and enjoin its enforcement. (App.8 ¶ 34; App.26 ¶ 85.) *Ex parte Young*'s narrow immunity exception is inapplicable to PhRMA's claim because takings claims necessarily involve the state as the real, substantial party in interest, and because such an order would interfere with the state's special sovereignty interest to take private property for a public purpose.

The Takings Clause is unique. The power to take private property for public use belongs to every independent government as an incident of sovereignty and requires no constitutional recognition. *United States v. Jones*, 109 U.S. 513, 518 (1883). The Fifth Amendment's assurance of just compensation for the property taken merely limits use of that power. *Id*.; *First Eng.*, 482 U.S. at 314. It is the failure to compensate for the taking, not the taking itself, that gives rise to a takings claim. *See Knick*, 139 S. Ct. at 2173, 2177; *First Eng.*, 482 U.S. at 315. And, just compensation under the Fifth Amendment is the same as traditional money damages. *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687, 710, (1999), *Seven Up Pete Venture v. Schweitzer*, 523 F.3d 948, 956 (9th Cir. 2008). As such, public officials are immune from suits in federal court seeking just compensation or inverse condemnation, despite the *Ex parte Young* exception. *Ladd v. Marchbanks*, 971 F.3d 574, 578-81 (6th Cir. 2020), *cert. denied*, 141 S. Ct. 1390 (2021); *Seven Up Pete*, 523 F.3d at 956.

Likewise, the *Ex parte Young* exception should not apply when a plaintiff seeks equitable relief requiring the court to determine whether an uncompensated taking occurred. Because the essence of all takings claims is that the plaintiff failed to receive just compensation (i.e., damages) for a governmental action, they necessarily involve the State as the real, substantial party in interest. Thus, the Sixth Circuit has recognized that a plaintiff can use any finding that a taking occurred to

require a state to pay the plaintiff for the alleged taking of their property, which is an improper workaround to the States' sovereign immunity. *Ladd*, 971 F.3d at 581. Further, under *Ex parte Young*, federal courts are limited to merely ordering public officials to adhere to the Constitution. For an alleged taking, therefore, a court would be limited to ordering payment of just compensation; not preventing a taking in the first instance. The state would be the real, substantial party in interest to an order for compensation, making *Ex parte Young* inapplicable. *Va. Off. for Prot. & Advoc*., 563 U.S. at 255; *Treleven v. Univ. of Minn.*, 73 F.3d 816, 818 (8th Cir. 1996).

Finally, *Ex parte Young* is inapplicable where special sovereignty interests are implicated. *Coeur d'Alene Tribe of Idaho*, 521 U.S. at 281, 287. Taking private property for public use is a special sovereignty interest. *Jones*, 109 U.S. at 518. Enjoining a public official from taking property where just-compensation remedies are available would improperly prohibit the state from proceeding with a valid policy and interfere with the state's right as a sovereign to take private property for a public purpose. *See id.*; *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005) ("[T]he Takings Clause presupposes that the government has acted in pursuit of a valid public purpose.") The *Ex parte Young* immunity exception should not permit federal courts to prevent states from exercising their sovereign right to take when just compensation remedies are available.

The *Ex parte Young* immunity exception is incompatible with PhRMA's takings claims.[12] The relief PhRMA seeks will necessarily impact the State as the real, substantial party in interest and prevent it from exercising its sovereign right to take. For the foregoing reasons—and because equitable relief is inappropriate for a takings claim—the *Ex parte Young* exception is inapplicable here and the Board members are immune from this suit under the Eleventh Amendment. Sovereign immunity is yet another independent basis upon which this court may affirm the district court's dismissal of PhRMA's Complaint.

## IV. THIS COURT LACKS JURISDICTION TO DECIDE PHRMA'S SUMMARY JUDGMENT MOTION IN THE FIRST INSTANCE.

The district court did not reach the merits of PhRMA's claim, holding that its motion for summary judgment was moot because PhRMA lacked standing. (Add.14.) PhRMA seeks an extraordinary remedy in its appeal. Not only does PhRMA ask the Court to reverse the district court's dismissal, but it also insists that the Court decide the merits of its takings claim and grant sweeping discretionary equitable relief halting the Act's life-saving insulin-affordability programs. Even if this Court holds dismissal was improper, there is no principled basis to remove the merits decision from the district court and decide it for the first time on appeal.

[12] Appellees acknowledge that courts have allowed takings claims seeking equitable relief to proceed under *Ex parte Young*, but the cases Appellees reviewed did not delve into the uniqueness of the Takings Clause as discussed here.

This Court's jurisdiction is limited to review of final district court decisions. 28 U.S.C. § 1291. With the exception of jurisdictional questions, "[t]he district courts decide federal questions in the first instance, and we review their decisions." *Cavegn*, 223 F.3d at 831 (internal citation omitted); *see also Bacon v. Liberty Mut. Ins. Co.*, 575 F.3d 781, 785 (8th Cir. 2009) (declining to decide issue not reached by district court because it granted a motion to dismiss). This Court lacks jurisdiction to review PhRMA's summary judgment motion, because there is no final district court decision to review.

PhRMA's request that this Court exercise original jurisdiction over its summary judgment motion is especially inappropriate because PhRMA seeks equitable relief, a remedy traditionally committed to the trial court's discretion. "The decision to grant or deny permanent injunctive relief is an act of equitable discretion by the district court, reviewable on appeal for abuse of discretion." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). A declaratory judgment is even more a matter of district court discretion. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 136 (2007) (stating the federal declaratory-relief law's permissive language gives court substantial discretion whether to declare litigant's rights). In the proceedings below, the Board members argued PhRMA had not met its burden to demonstrate that it was entitled to injunctive relief or that a declaratory judgment was necessary and appropriate. (Doc. 66, at 37-43.) These arguments

must be considered in the first instance by the district court. *MedImmune*, 549 U.S. at 136 (holding, where the district court had not yet considered the issue, that it would be "imprudent for us to decide whether the District Court should, or must, decline to issue the requested declaratory relief").

PhRMA cites *Murray v. American Family Mutual Insurance*, 429 F.3d 757 (8th Cir. 2005), to argue that this Court may decide its summary judgment motion. (Appellant's Br. 24, 49.) PhRMA's reliance on that case is misplaced. *Murray* involved an appeal from *a summary judgment decision* and did not involve claims for equitable relief. In reviewing that decision, this Court held that it could reach sub-issues not addressed by the district court, but which the parties briefed in the summary judgment motion that the district court decided. *Id.* at 765. *Murray* and similar cases, where a district court has already evaluated the merits of the parties' disputes, do not apply here, where PhRMA's summary judgment motion seeking equitable relief was not considered at all, but rather denied as moot because the district court dismissed on jurisdictional grounds. (Add.14.)

Additionally, addressing the merits of PhRMA's summary judgment motion rather than remanding would violate "the fundamental principle of judicial restraint" that courts should not consider an issue of "constitutional law in advance of the necessity of deciding it." *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 450 (2008) (cleaned up); *see also United States v. Turechek*,

138 F.3d 1226, 1229 (8th Cir. 1998) (stating federal courts have strong duty to avoid deciding constitutional issues unless necessary). Despite PhRMA's contention, the constitutional question in this matter is not a straightforward legal question. Takings cases are "among the most litigated and most perplexing in current law." *Apfel*, 524 U.S. at 541 (Kennedy, J., concurring and dissenting in part).

PhRMA brought its motion fewer than thirty days after commencing suit and before any discovery occurred. The Board members argued that the motion was premature and, if the court concluded it had jurisdiction, discovery was needed to adequately defend the motion. (Docs. 66, at 41, 44; App.33-34, ¶¶ 1-5.) It was within the court's discretion whether to continue PhRMA's motion to allow for discovery, but it did not reach that issue. *See Toben v. Bridgestone Retail Operations, LLC*, 751 F.3d 888, 894 (8th Cir. 2014) (reviewing Rule 56(d) decision for abuse of discretion); *Shelton v. Bledsoe*, 775 F.3d 554, 568 (3d Cir. 2015) (holding court's failure to consider Rule 56(d) declaration was abuse of discretion.)

PhRMA argues additional facts are unnecessary because it alleged a *per se* taking. (Appellant's Br. 49.) But labelling an act as a *per se* taking is not determinative. *See* Echeverria, *supra* 54 U.C. Davis L. Rev. at 733-34 (explaining that a literal *per se* rule for physical takings does not exist and stating that the Court's physical takings decisions include language and analysis pointing to a more nuanced, multifactorial approach). PhRMA relies on the Supreme Court's decision in *Horne*

to support its contention that additional facts are unnecessary. (Appellant's Br. 49-50). But in *Horne*, the Court analyzed the specific facts of the case and indicated it may reject a physical takings claim based on different facts. *See Horne*, 576 U.S. at 361-67; Echeverria, *supra* 54 U.C. Davis L. Rev. at 733-34. *Horne* is distinguishable and is not controlling in this case. (Doc. 66, at 23, 28-30.)

As the Board members argued below, the Act does not effect a taking due to the specific unique facts of this case, including the insulin manufacturers' oligopoly on insulin, their creation of the insulin-affordability crisis, and Minnesota's licensing requirements. (Doc. 66, at 22-36.) Numerous cases show that courts must consider claims of alleged physical takings on their particular facts in light of the economic factors and social harms that surround them, and these cases establish that the Act at issue here does not effect a taking. *See, e.g.*, *Concrete Pipe & Prod. of Cal., Inc. v. Constr. Laborers Pension Tr. for S. Cal.*, 508 U.S. 602 (1993); *Connolly v. Pension Ben. Guar. Corp.*, 475 U.S. 211 (1986); *Ruckelshaus*, 467 U.S. at 1016; *Miller v. Schoene*, 276 U.S. 272 (1928); *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442 (8th Cir. 1984); *Sierra Med. Servs. All. v. Kent*, 883 F.3d 1216 (9th Cir. 2018); *Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121 (1st Cir. 2009). Rather, the Act is a public health and safety law necessary to abate some of the harm caused by the insulin manufacturers; an exchange the manufacturers agreed to make for the benefit of obtaining a drug-manufacturers

license; and a public program regulating the manufacturer's use of the insulin. (*See* Doc. 66, at 22-36.)

The purpose of the Fifth Amendment's guarantee was "to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole." *Armstrong v. United States*, 364 U.S. 40, 49 (1960). Under this case's particular facts, fairness and justice require that the manufacturers who caused the insulin crisis—not the public at large—bear the responsibility of protecting people who cannot afford the exorbitant cost of insulin. But the district court has not yet considered these arguments, and it would be inappropriate for this Court to bypass the district court to reach a constitutional question that it need not decide.

Even if this Court were permitted, and inclined, to address the merits of the takings question before the district court does, PhRMA has not met its burden to show that it is entitled to injunctive relief as a matter of law. This Court cannot enjoin the Act in the absence of irreparable harm and a demonstration that the balance of harms and the public interest favor an injunction. The caselaw PhRMA cites to assert that it need not prove these factors is inapposite and distinguishable; the cases all arise from different constitutional doctrines—such as free speech, abortion, and preemption—and as discussed above, the Takings Clause is unique. PhRMA cannot obtain injunctive relief without meeting its burden to show

these factors, and it has put forward no facts proving irreparable harm or that the Act harms the manufacturers, whose sales of insulin yield $24 billion in annual revenue, more than it serves the public interest of helping Minnesotans with diabetes to stay alive.

By seeking a determination of its summary judgment motion, PhRMA asks this Court to "assume a role reserved for the district court." *Cavegn*, 223 F.3d at 831. But this Court lacks original jurisdiction to decide PhRMA's motion for summary judgment in the first instance. If the Court holds the district court had jurisdiction to hear PhRMA's claim, it should remand the case to allow the district court to exercise that jurisdiction.

## CONCLUSION

The district court properly dismissed PhRMA's complaint for lack of standing as the equitable relief PhRMA seeks for its Takings Clause claim is foreclosed. In addition, PhRMA lacks associational standing to bring its takings claim and the Minnesota Board of Pharmacy members are immune from suit under the Eleventh Amendment. As such, this Court should affirm dismissal of this case. If, however, this Court determines PhRMA has met its burden to prove jurisdiction, it should remand the matter to the district court to decide the case on its merits.

Dated: June 22, 2021

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**CERTIFICATE OF COMPLIANCE**
**WITH FED. R. APP. P. 32**

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 12,118 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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 this brief has been prepared in a proportionally spaced typeface using Microsoft Word for 365 in 14 pt. Times New Roman font.

/s/**Sarah L. Krans**
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**CERTIFICATE OF COMPLIANCE**
**WITH 8th Cir. R. 28A(h)(2)**

The undersigned, on behalf of the party filing and serving this brief, certifies that the brief has been scanned for viruses and that the brief is virus-free.

**/s/Brenda Hanson**
BRENDA HANSON

## CERTIFICATE OF SERVICE

I certify that I caused this document to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the appellate CM/ECF system on June 22, 2021. All participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

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