UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Pharmaceutical Research and Manufacturers of America, Plaintiff, v. Stuart Williams, et al., Defendants.	Case No. 0:20-cv-01497-DSD-DTS **MEMORANDUM SUPPORTING DEFENDANTS' RULE 56(D) MOTION TO DENY OR CONTINUE PLAINTIFF'S SUMMARY JUDGMENT MOTION**

The Eighth Circuit recently remanded this case after this Court previously dismissed Plaintiff Pharmaceutical Research and Manufacturers of America's (PhRMA) claims that Minnesota's insulin safety-net program amounts to an unconstitutional taking. PhRMA then immediately moved for summary judgment. (Doc. 93.) Because PhRMA's motion is premature, the Court should either deny it or continue the hearing and briefing to allow for discovery.

Despite PhRMA's fact-intensive, twenty-nine page complaint and the three years that have passed since drafting it, PhRMA asks this Court to grant it the extraordinary remedy of declaring unconstitutional and enjoining a life-saving state law without allowing the defendants (members of the Minnesota Board of Pharmacy) *any* discovery. PhRMA's request is staggering given the complexity of its claim and the extraordinary relief it seeks.[1]

[1] *See E. Enters. v. Apfel*, 524 U.S. 498, 541 (1998) (stating that takings cases are "among the most litigated and most perplexing in current law") (Kennedy, J., concurring and dissenting in part); *Knick v. Twp. of Scott*, 139 S. Ct. 2162, 2176, 2179 (2019) (stating equitable relief is typically foreclosed in takings claims).

PhRMA initiated this action. The defendants require and are entitled to discovery to properly defend the law.

FACTS

In June 2020, the day before the Alec Smith Insulin Affordability Act[2] became operational, PhRMA sued the Board members, alleging that the Act creates an unconstitutional taking. (Doc. 1.) Rather than seek compensation, however, PhRMA sought to enjoin enforcement of certain provisions of the Act and to obtain a declaratory judgment that those provisions effect takings. (*Id.*)

Shortly thereafter, the Board members moved to dismiss, and PhRMA moved for summary judgment. (Docs. 12, 14.) The Board members argued that PhRMA's claims for equitable relief were foreclosed, PhRMA lacked standing, and the Board members were immune from suit. (Doc. 16.) The Board members also argued that PhRMA's summary-judgment motion was premature because they had not had an opportunity to engage in any discovery.[3] (Doc. 66.) They provided a supporting declaration showing that, without discovery, they could not present facts essential to justify their position. (Doc. 68.) This Court dismissed the action, holding that PhRMA lacked standing to pursue equitable relief on its takings claim and denying PhRMA's summary-judgment motion as moot. (Doc. 81 at 14.) It did not reach the parties' other arguments. (*Id.*)

[2] Minn. Stat. § 151.74.

[3] The Board members also argued that the motion was moot because dismissal was proper, and that PhRMA failed to establish it was entitled to relief. (Doc. 66.)

PhRMA appealed. (Doc. 85.) In April 2023, the Eighth Circuit reversed and remanded. *Pharm. Rsch. & Mfrs. of Am. v. Williams*, 64 F.4th 932, 936 (8th Cir. 2023). As required by the procedural posture, the Eighth Circuit accepted the factual allegations in PhRMA's complaint as true and viewed the facts in the light most favorable to PhRMA. *Id.* at 945 n.7. The court denied the Board members' petition for rehearing.

The parties have not yet had a Rule 16 or 26 conference because PhRMA has refused to agree to one. (Second Krans Decl. ¶ 6.[4]) On July 12, PhRMA moved for summary judgment and preemptively argued that discovery is unnecessary. (Docs. 93, 95 at 29-30.) The hearing on PhRMA's motion is scheduled for November 8. (Doc. 104.)

ARGUMENT

Summary judgment is appropriate only when the non-moving party has been able to conduct discovery. *Robinson v. Terex Corp.*, 439 F.3d 465, 467 (8th Cir. 2006). Without discovery, summary judgment "forces the non-moving party into a fencing match without a sword or mask." *McCray v. Md. Dep't of Transp.*, 741 F.3d 480, 483 (4th Cir. 2014). For this reason, when the non-moving party shows by declaration that it cannot present facts essential to justify its opposition, a court may (1) defer considering the motion or deny it; (2) allow time for discovery; or (3) issue any other appropriate order. Fed. R. Civ. P. 56(d).[5] Rule 56(d) provides a safeguard against an improvident or premature grant of

[4] The parties did not have a pretrial conference in 2020 because the defendants' motion to dismiss was pending. (Doc. 80 (cancelling original pretrial conference); Second Krans Decl. ¶ 4.)

[5] A party may invoke Rule 56(d) (formerly Rule 56(f)) through a motion for a continuance accompanied by an affidavit. *Nolan v. Thompson*, 521 F.3d 983, 986 (8th Cir. 2008).

summary judgment and "should be applied with a spirit of liberality." *U.S. ex rel. Bernard v. Casino Magic Corp.*, 293 F.3d 419, 426 (8th Cir. 2002). When failing to allow discovery deprives the nonmovant of a fair chance to oppose the motion, summary judgment is improper and will be reversed. *Iverson v. Johnson Gas Appliance Co.*, 172 F.3d 524, 530 (8th Cir. 1999).

PhRMA's summary-judgment motion is premature because the Board members have not been able to obtain any discovery. Without a Rule 26(f) conference, the Board members cannot seek discovery from any source. *See* Fed. R. Civ. P. 26(d)(1) (prohibiting discovery before parties have conferred as required by Rule 26(f)). No scheduling conference has occurred, and the parties have yet to exchange initial disclosures. (Second Krans Decl. ¶ 8.) The Board members need fact discovery to defend this case and respond to PhRMA's motion.

I. DISCOVERY IS NECESSARY TO DETERMINE PHRMA'S CONTINUED STANDING TO MAINTAIN THIS ACTION.

Discovery is necessary to determine whether PhRMA continues to have standing to bring this action on behalf its members, or whether its claims for prospective relief are, or will be, moot. Federal courts have subject-matter jurisdiction only over "cases and controversies." U.S. Const. art. III, § 2. To maintain a case or controversy, a plaintiff must have standing throughout the litigation. *Religious Sisters of Mercy v. Becerra*, 55 F.4th583, 601 (8th Cir. 2022). When a case no longer presents an actual, ongoing case or controversy, the case is moot and the federal court lacks jurisdiction to hear it. *Hickman v. Missouri*, 144 F.3d 1141, 1142 (8th Cir. 1998). A plaintiff seeking injunctive relief must show that

he "faces a threat of ongoing or future harm" to have standing. *Park v. Forest Serv. of the U.S.*, 205 F.3d 1034, 1037 (8th Cir. 2000). That a court finds standing in the context of a motion to dismiss does not preclude a court from reassessing standing at the summary-judgment stage. *Christian Labor Ass'n v. City of Duluth*, No. 21-227, 2023 WL 3996240, at *4, 7-9 (D. Minn. June 14, 2023) (concluding that discovery established plaintiffs ultimately lacked standing), *appeal docketed*, No. 23-2450 (8th Cir. June 16, 2023).

Here, PhRMA's continued standing to maintain this case is in doubt. It presented no evidence of standing in its new summary-judgment motion. (Doc. No. 95 at 12 (citing self-reported 2022 data).) And even if it attempts to remedy that deficiency, the Board members deserve the opportunity to vet that information in discovery, particularly given changes in the insulin-pricing landscape and the manufacturers' public statements.

Any manufacturer with an annual gross revenue of $2 million or less from insulin sales in Minnesota is exempt from the Act. Minn. Stat. § 151.74, subd. 1(c). Also, an insulin product is exempt from the Act "if the wholesale acquisition cost of the insulin is $8 or less per milliliter or applicable National Council for Prescription Drug Plan billing unit, for the entire assessment time period, adjusted annually based on the Consumer Price Index." *Id.*, subd. 1(d). PhRMA brought this action on behalf of its members, the three largest insulin manufacturers, Sanofi-Aventis U.S. LLC, Eli Lilly and Company, and Novo Nordisk Inc., who it alleged were subject to the challenged Act. (Doc. 1, ¶ 13.) To support its summary-judgment motion in 2020, PhRMA filed generic declarations from the three manufacturers, perfunctorily stating that they and their insulin products were subject to the Act because their annual gross revenue from selling insulin products in Minnesota

exceeded $2 million in 2019 and their insulin products had wholesale acquisition costs[6] ("WAC") of more than $8 per milliliter. (Docs 29-31.) The manufacturers did not specify either their annual gross revenue from Minnesota sales or their products' WAC. *Id.*

In the three years since PhRMA started this lawsuit, the insulin landscape has changed dramatically. In 2023 alone, each manufacturer announced significant insulin price reductions. For example, on March 1, Eli Lilly announced that it was reducing prices for its most prescribed insulins by 70% and expanding a program that caps patient out-of-pocket costs at $35 or less per month for both insured and uninsured patients. (Second Krans Decl. ¶ 12, Ex. 1.) As of this spring, Eli Lilly also appears close to settling a class-action lawsuit against the three insulin manufacturers regarding their insulin prices. *In re Insulin Pricing Litig.*, No. 2:17-cv-00699-BRM-LHG (D.N.J.) (May 26, 2023 Doc. Nos. 639-639-7.) The settlement, if approved by the court, requires Eli Lilly to make certain insulin products available to class members for no more than $35 (out of pocket) a month for the next four years. *Id.*, Doc. 639-1 at 16.

Novo Nordisk and Sanofi followed Eli Lilly's lead in announcing price cuts to insulin products. On March 14, Novo Nordisk announced that it is lowering the U.S. list prices of several insulin products by up to 75%, effective January 1, 2024. (Second Krans Decl. ¶ 12, Ex. 1.) Two days later, Sanofi announced that it is reducing its list prices for its two lead insulin products by 78% and 70%. (*Id.*) It is also establishing certain $35 per month caps on out-of-pocket costs. (*Id.*) Sanofi's changes take effect on January 1. (*Id.*)

[6] Wholesale acquisition cost is also known as the list price.

Despite these changes, and despite seeking a permanent injunction, PhRMA failed to present any updated declarations showing that its members are and will continue to be subject to the Act. The Board members are entitled to discovery on these issues. If the manufacturers are exempt or soon will become exempt from the Act, their claims for prospective equitable relief are non-justiciable and this Court lacks jurisdiction.

II. DISCOVERY IS NECESSARY TO DEFEND THE MERITS OF PHRMA'S CLAIM THAT THE ACT EFFECTS A TAKING.

Discovery is also necessary for the Board members to defend the constitutionality of Minnesota's law against PhRMA's allegation that the Act effects a taking. The Board members maintain that the Act does not effect a taking because it abates a nuisance maintained by the insulin manufacturers, is a voluntary exchange for the benefit of a drug-manufacturer license, and is a public program that lawfully adjusts economic benefits or burdens. (Doc. 66 at 22-34.) PhRMA asserts that these defenses do not apply to per se physical taking claims, so discovery is unnecessary. (Doc. 95 at 21-29.)

PhRMA is wrong. During the appeal of this lawsuit, the Supreme Court confirmed that abating a nuisance and ceding property rights as a condition of receiving certain benefits, such as a license, generally do not constitute takings, even when involving alleged per se physical takings. *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2079-80 (2021).[7] In *Cedar Point Nursery*, the Court held that a California regulation allowing labor

[7] PhRMA notably did not cite *Cedar Point Nursery* in its recent summary-judgment memorandum despite citing it multiple times in its reply brief to the Eighth Circuit.

organizations to access agricultural employers' property to discuss unionization with employees constituted a per se physical taking. *Id*. at 2080.

In response to the minority opinion's concerns that the holding improperly expanded takings jurisprudence, the Court identified three broad frameworks in which physically interfering with property rights still does not constitute a taking. *Id.* at 2078-80. First, trespasses are still not takings. *Id.* at 2078. Second, "government-authorized physical invasions" consistent with longstanding restrictions on property rights are not takings. *Id*. at 2079. For example, requiring a property owner to abate a nuisance is not a taking because the owner never had a right to engage in the nuisance in the first place. *Id.* Other examples include entering property for a public or private necessity, effecting an arrest, enforcing the criminal law, and conducting reasonable searches consistent with the Fourth Amendment and state law. *Id.* Third, the government may require property owners to cede property rights as a condition of receiving certain benefits, such as permits, licenses, or registrations, so long as the condition bears an "essential nexus" and "rough proportionality" to the impact of the proposed use. *Id*. This is why health and safety inspections typically are not takings. *Id*.

Based on the law and on basic principles of fairness, the Court should allow the Board members to conduct discovery. PhRMA should not be able to sue the defendants and then attempt to quickly seek a judgment on the merits before they have an opportunity to adequately defend the case.

A. Discovery is Necessary to Present Facts Essential to the Board Members' Nuisance Defense.

Even before *Cedar Point Nursery*, the Board members invoked the nuisance exception to takings because the Act simply attempts to abate the public nuisance maintained and permitted by the insulin manufacturers. The nuisance exception to takings claims is well recognized and long standing. *See*, *e.g.*, *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1031-32 (1992); *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 490-92 (1987); *Miller v. Schoene*, 276 U.S. 272, 279-80 (1928); *Hadacheck v. Sebastian*, 239 U.S. 394, 410-14 (1915). And *Cedar Point Nursery* confirmed that, contrary to PhRMA's position, requiring a property owner to abate a nuisance explicitly falls outside the per se takings framework. 141 S.Ct. at 2079-80. As such, the Board members' nuisance defense is a viable legal defense to PhRMA's per se physical takings claim, entitling the Board members to discovery.[8]

Under Minnesota law, a person or entity maintains a public nuisance by intentionally maintaining or permitting a condition that "unreasonably annoys, injures or endangers the safety, health, morals, comfort, or repose of any considerable number of members of the public." Minn. Stat. § 609.74 (2022). Private property rights are

[8] Before *Cedar Point Nursery*, the nuisance exception had been applied to alleged physical takings. *John R. Sand & Gravel Co. v. United States*, 60 Fed. Cl. 230, 239 (2004), *rev'd and vacated on other grounds* 457 F.3d 1345, 1353 (Fed. Cir. 2006) (holding claims were time barred), *aff'd* 552 U.S. 130, 128 S. Ct. 750 (2008). Since *Cedar Point Nursery*, at least one court has applied the nuisance exception to a physical takings claim. *Grater v. Damascus Twp. Trustees*, 614 F. Supp. 3d 591, 600 (N.D. Ohio 2022), *aff'd sub nom. Grater v. Damascus Twp.*, No. 22-3616, 2023 WL 3059080 (6th Cir. Apr. 24, 2023) (holding that township did not effect taking by removing equipment, vehicles, and materials from plaintiffs' property).

"subservient to the public right to be free from nuisances which may be abated without compensation." *State v. Guilford*, 219 N.W. 770, 773 (Minn. 1928). The sale of legal products can be a public nuisance. *Minnesota v. Fleet Farm LLC*, No. 22-CV-02694 (JRT/JFD), 2023 WL 4203088, at *12 (D. Minn. June 27, 2023).

The Board members' nuisance defense is well founded. The existence of an insulin-affordability crisis is well known. The three largest insulin manufacturers—who manufacture nearly all insulin in the United States—have caused and maintained this crisis.

Insulin was discovered over one hundred years ago by Canadian scientists who sold their U.S. patents to a university for one dollar. (Doc. 68-1 at 5.) The university then allowed manufacturers to produce insulin royalty-free. (*Id.*) Unfortunately, the manufacturers used the university's goodwill to profit significantly. The manufacturers have complete control over setting the list price (WAC) for their insulin products.[9] And they have exploited that control by exponentially increasing the cost of insulin over the past two decades.[10] Since the 1990s, costs have increased by more than 1,200%.[11] While a vial of analog insulin likely costs between $2 and $18 to manufacture,[12] it retails in the $300 range.[13] These price increases are unrelated to any significant advances in the efficacy of the drugs and have dramatically exceeded rates of inflation, including health

[9] Staff of S. Finance Comm., *Insulin*: *Examining the Factors Driving the Rising Cost of a Century Old Drug*, at 5 (Jan. 14, 2021) ("Senate Report"), https://perma.cc/HB4N-WNK4.
[10] Docs. 68-1 at 6, 68-2 at 1, 68-4 at 2-3.
[11] Doc. 68-4 at 3.
[12] Doc. 68-3 at 3.
[13] Ritu Prasad, *The Human Cost of Insulin in America*, BBC NEWS (March 14, 2019), https://perma.cc/22XA-GK8A.

care inflation.[14] Many articles, professional publications, congressional reports, committee hearings, law review articles, and lawsuits address the various unethical—and illegal—ways in which the insulin manufacturers have maintained and permitted artificially inflated prices for insulin.[15] Since PhRMA commenced this action, at least seven states, three counties, and Puerto Rico have sued the three insulin manufacturers for their roles in the insulin pricing scheme.[16] And, in 2021, the U.S. Senate Finance Committee investigated insulin pricing, reviewing over 100,000 pages, mostly from the manufacturers.[17]

In maintaining and permitting their insulin-pricing scheme, the manufacturers have injured and endangered the health, safety, and comfort of the millions of Americans and hundreds of thousands of Minnesotans with diabetes, their families, healthcare and public-health professionals, insureds, and taxpayers.[18] An estimated one in four people with

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[14] *See,* Senate Report, *supra* note 9 at 5, 41.

[15] *See, e.g.*, *id.*; Docs. 68-1 to 68-4; Fran Quigley, *Tell Me How It Ends: The Path to Nationalizing the U.S. Pharmaceutical Industry*, 53 U. Mich. J.L. Reform 755, 798 (2020); *In re Insulin Pricing Litig.*, No. 2:17-cv-00699-BRM-LHG (D.N.J.); *Minnesota by Ellison v. Sanofi-Aventis U.S. LLC*, No. 2:18-cv-14999-BRM-LHG (D.N.J.); *California v. Eli Lilly & Co.*, No. 23-ST-CV-00719 (Los Angeles Super. Ct.); *Louisiana v. Sanofi-Aventis U.S. LLC*, No. 3:2023-cv-00302 (M.D. La.); *Government of Puerto Rico v. Eli Lilly & Co.*, No. SJ2023CV00319 (Ct. of First Instance); *Jackson Cnty., Mo. v. Eli Lilly & Co.*, No. 4:2023-cv-00206 (W.D. Mo.); *Griffin v. Eli Lilly & Co.*, No. 4:22-cv-00549 (E.D. Ark.); *Illinois ex rel. Raoul v. Eli Lilly & Co.*, No. 1:23-cv-00170 (N.D. Ill.);*Kansas ex. rel. Kobach v. Eli Lilly & Co.*, No. 5:23-cv-04002 (D. Kan.); *Mississippi ex. rel. Fitch v. Eli Lilly & Co.*, No. 3:21-cv-00674 (S.D. Miss.); *Montana ex. rel. Knudsen v. Eli Lilly & Co.*, No. 6:22-cv-00087 (D. Mont.); *Cnty. of Albany, N.Y. v. Eli Lilly & Co.*, No. 1:22-cv-00981 (N.Y.N.D.); *Lake Cnty., Ill. v. Eli Lilly & Co.*, No. 1:2023-cv-02402 (N.D. Ill.).

[16] *Id.*

[17] Senate Report, *supra* note 9 at 4, 88.

[18] In 2020, approximately 390,000 adult Minnesotans had been diagnosed with type 1 or 2 diabetes. Minn. Dep't of Health *Diabetes in Minnesota*, https://perma.cc/7V42-PDN6.

diabetes have had to ration insulin due to its unaffordable price.[19] Rationing is dangerous and can lead to a variety of health complications such as diabetic ketoacidosis.[20] And in some cases—like that of Minnesotans Alec Smith and Jesimya David Scherer-Radcliff—death.[21] In addition to the needless and tragic loss of life, insulin rationing increases costs to, and overcrowds, the health care system by increasing preventable complications. If Americans with diabetes could adhere to their diabetes medication, it would save an estimated $8.3 billion in direct medical costs per year by averting one million emergency department visits and 618 hospitalizations.[22] But because of the exorbitant prices that manufacturers charge for insulin, that adherence is unfortunately not attainable for all.

PhRMA then brought this lawsuit and seeks to block discovery. This is just another attempt by PhRMA and its members to avoid transparency and accountability for insulin manufacturers' roles in creating and maintaining the insulin-affordability crisis. Discovery is necessary for the Board members to develop and present facts supporting their nuisance

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[19] *See* Senate Report, *supra* note 9, at 14; Darby Herkert et al., *Cost-Related Insulin Underuse Among Patients With Diabetes,* 179 JAMA INTERN MED. 112–14 (2019), https://perma.cc/MF8V-6VD9; Elizabeth Pfiester et al., *Costs And Underuse Of Insulin And Diabetes Supplies: Findings From The 2020 T1International Cross-Sectional Web-Based Survey*, 179 Diabetes Research & Clinical Practice 1, 6 (Sept. 2021), https://perma.cc/KV6H-QCPF.

[20] Senate Report, *supra* note 9 at 13, 14; Doc. 68-2 at 1.

[21] Doc. Nos. 68-1 at 6, 68-2 at 1, 68-4 at 2; Adrienne Broaddus, *Family Says 21-year-old Son Died Rationing Insulin*, KARE11 (July 12, 2019), https://perma.cc/9UE4-4NKX; *Alec Smith Insulin Affordability Act*: *Hearing on H.F. 3100 Before the Commerce Comm.*, 2020 Leg., 91st Sess. (Minn. Feb. 11, 2020) (statement of Nicole Smith-Holt at 8:08-11:29), https://www.house.leg.state.mn.us/hjvid/91/892535.

[22] *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. 1835, 1842 (2012), https://perma.cc/XA5F-UJZ4.

defense. Examples of potentially relevant information include: manufacturers' insulin pricing, including their price increases, and the bases for the price increases; manufacturers' actions to maintain their pricing and oligopoly over the insulin market; the actual costs to manufacture insulin; the number of insulin sales in Minnesota; the manufacturers' gross and net insulin sales in Minnesota; the manufacturers' profits from insulin sales in Minnesota; the number of people seeking assistance through the manufacturers' programs and the Act; the number of people receiving and being denied assistance through the manufacturers' programs and the Act; and the amount of insulin and financial assistance provided through the manufacturers' assistance programs and under the Act. (Second Krans Decl. ¶¶ 14-15.) The Board members also need discovery on the impact of the manufacturers' insulin pricing on Minnesotans, including Minnesotans forced to ration insulin because of artificially high insulin prices and the resulting consequences from rationing. (*Id.*)

Given the emerging evidence of, and the real-life impact from, manufacturers' inflated insulin prices, the defendants' nuisance defense is well founded, and discovery is not a fishing expedition. Nor would it be overly burdensome on PhRMA or the manufacturers as they are already litigating their insulin pricing in various suits and engaging in discovery.[23]

[23] *See supra*, note 15.

B. Discovery is Necessary to Present Facts Essential to the Board Members' Licensing-Condition Defense.

The Board members, relying on *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984), previously argued that the Act did not effect a taking because complying with the Act was a voluntary exchange for a government benefit, i.e., a Minnesota drug-manufacturer license. (Doc. 66 at 28-31.) Minnesota requires drug manufacturers, including insulin manufacturers, to be licensed before they can act as a drug manufacturer in Minnesota. Minn. Stat. § 151.252, subd. 1. To obtain or renew a license, each manufacturer must agree to operate in a manner prescribed by state law, including following the Act. *Id*., subd 1(d). The three main insulin manufacturers obtained and renewed their drug-manufacturer licenses, allowing them to ship their drugs into Minnesota and do business with accounts in Minnesota. (Doc. 67.) In exchange for these benefits, they agreed to abide by the Act. Minn. Stat. § 151.252, subd. 1(d); Minn. R. 6800.1400, Doc. 67.

PhRMA has argued that *Monsanto* is inapplicable because, there, the law did not cause a per se physical taking.[24] (Doc. 95 at 24-26.) *Cedar Point Nursery*, however, cited *Monsanto* favorably and reiterated that requiring property owners to transfer property as a condition of receiving a government benefit falls outside the per se takings framework and may not constitute a taking.[25] *Cedar Point Nursery*, 141 S. Ct. at 2079. The Court

[24] The Board members disagree because *Monsanto* involved an alleged physical taking of Monsanto's trade secret.

[25] *See Valancourt Books, LLC v. Perlmutter*, 554 F. Supp. 3d 26, 36 (D.D.C. 2021 (discussing *Monsanto* and *Cedar Point Nursery* in upholding law requiring publishers to provide a copy of new work eligible for copyright to Copyright Office under licensing-condition exception to takings claim), *appeal docketed*, No. 21-5203 (D.C. Cir. Sept. 23, 2021).

identified permits, licenses, and registrations as examples of government benefits that may be granted with conditions to cede property rights without causing a taking. *Id.* In the case of a licensing condition, the inquiry is whether the condition bears an "essential nexus" and "rough proportionality" to the impact of proposed use of the property. *Id*.

Whether the Act's requirements are roughly proportionality to the specific interest the government seeks to protect through the licensing process is a fact-specific inquiry requiring discovery. Various facts are necessary to analyze whether the Act's impact on manufacturers is roughly proportional to the burdens placed on consumers by the manufacturers' sales of overpriced insulin in Minnesota. Some examples of relevant facts are: the WAC, manufacturers' net prices, and manufacturing costs of the insulin sold in Minnesota and provided under the Act; the number of individuals purchasing insulin in Minnesota; Minnesotans' out-of-pocket costs for insulin; the number of Minnesotans who have used or tried to use the Act; and harms suffered by Minnesotans from inflated insulin prices.[26] (Second Krans Decl. ¶¶ 14-15.) Discovery on these facts is essential for the Board members to oppose PhRMA's summary judgment.

[26] Although the manufacturers submitted reports to the Board as required by the Act, the Board has not had an opportunity to verify the accuracy of their reports and knows of at least some inaccuracies. *See* Minn. Bd. of Pharm., *Report to the Legislature on the Minnesota Insulin Safety Net Program* 3 (Mar. 1, 2023) (stating that the numbers in Novo Nordisk's 2022 report were artificially inflated), available at https://perma.cc/3TN3-VDXF; Second Krans Decl. ¶ 11.

III. DISCOVERY IS NECESSARY TO DEFEND AGAINST PHRMA'S CLAIM FOR INJUNCTIVE RELIEF.

The Board members require discovery to have a fair chance to respond to PhRMA's claims for injunctive relief. "An injunction is a drastic and extraordinary remedy, which should not be granted as a matter of course." *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165 (2010). To obtain a permanent injunction, the moving party must show actual success on the merits. *Miller v. Thurston*, 967 F.3d 727, 735 (8th Cir. 2020). Even then, a court must consider three other factors to determine whether a permanent injunction is warranted: (1) the threat of irreparable harm to the moving party; (2) the balance of harms with any injury an injunction might inflict on other parties; and (3) the public interest. *Id.*

In addition to needing discovery to respond to the merits of PhRMA's claim, the Board members need discovery to defend against the three other injunction factors this Court must consider. Specifically, the Board members need discovery relevant to the following: the WAC, net prices, and manufacturing costs of the insulin sold in Minnesota and provided under the Act; the number of individuals purchasing insulin in Minnesota; the manufacturers' insulin revenue and net worth; how the manufacturers and their vendors have operated under the Act's urgent-need program (i.e., whether they reimbursed pharmacies or sent replacement insulin and details on any insulin or reimbursements provided); Minnesotans who used or tried to use the Act; Minnesotans' use of manufacturers' insulin programs; the WAC and net price of insulin provided to Minnesotans under manufacturers' programs; the amounts manufacturers receive for

insulin provided under their own programs; Minnesotans whose applications for assistance through the manufacturers' programs were denied; the degree and consequences of insulin rationing in Minnesota; and information on the manufacturers' recent and any further planned price reductions on insulin. (Second Krans Decl. ¶¶ 14-15.)

In addition to developing their defenses, the Board members are entitled to develop and vet the bases for PhRMA's factual positions, including PhRMA's assertions that the manufacturers will continue to be subject to the Act in the future; that its members will suffer irreparable harm; and that, if the Act is a taking, the manufacturers will be subject to a multiplicity of suits to recover just compensation. (*Id*.)

PhRMA attempts to avoid a fact issue by claiming that it is exempt from proving irreparable harm if the court finds a constitutional violation. (Doc. 95 at 30.) While this is true for some constitutional violations, it is not true for takings claims. *See Knick v. Twp. of Scott*, 139 S. Ct. 2162, 2176, 2179 (2019) (holding equitable relief generally unavailable for takings claims); *Wis. Cent. Ltd. v. Pub. Serv. Comm'n of Wis.*, 95 F.3d 1359, 1369 (7th Cir. 1996) (stating that plaintiff claiming takings "would be hard pressed to demonstrate either irreparable harm or an inadequate remedy at law.") That is because, unlike other constitutional deprivations, the Takings Clause provides both the cause of action and the remedy—just compensation. *Wis. Cent. Ltd.*, 95 F.3d at 1369. Automatic findings of irreparable harm have generally been limited to intangible injuries that result from violations of fundamental rights, such as free speech, association, and privacy. *Ne. Fla. Chapter of Ass'n of Gen. Contractors of Am. v. City of Jacksonville*, 896 F.2d 1283, 1285-86 (11th Cir. 1990) (refusing to presume irreparable harm for equal-protection violation

when damage to plaintiff was primarily economic); *Vaqueria Tres Monjitas, Inc. v. Irizarry*, 587 F.3d 464, 484-85 (1st Cir. 2009) (stating due process and equal protection violations do not automatically result in irreparable harm). Whether to grant an injunction in a takings case is a fact-intensive inquiry and an equitable decision within the Court's discretion. *Watkins v. Lawrence Cnty., Ark.*, No. 17-cv-272, 2023 WL 2760001, at *2, 4-6 (E.D. Ark. Mar. 31, 2023) (evaluating factual evidence and denying injunction after jury found taking), *appeals docketed*, Nos. 23-1939, -2110 (8th Cir. May 2 and 4, 2023).

PhRMA also claims that the Eighth Circuit has already found that the manufacturers' alleged injury is irreparable. (Doc. 95 at 25.) It did not. In evaluating the adequacy of Minnesota's inverse condemnation procedure, the Eighth Circuit accepted PhRMA's allegations as true and viewed the facts in the light most favorable to PhRMA. *Pharm. Rsch. & Mfrs. Ass'n*, 64 F.4th at 945 n.7. While PhRMA received the benefit of the doubt at the motion-to-dismiss stage, it bears the burden of proof and must now prove the allegations in its complaint.

Finally, PhRMA similarly argues that the Court can disregard the balance-of-harms and the public-interest injunction factors if the Act is unconstitutional. (Doc. 95 at 31.) The cases that PhRMA cites, however, are preemption cases. In takings cases, courts must consider the public interest. Courts of equity must act with caution when the taking involves large public interests and issuing an injunction may seriously thwart important governmental ends. *Hurley v. Kincaid*, 285 U.S. 95, 105 (1932). As such, discovery on all the injunctive relief factors is essential for the Board members to properly defend against PhRMA's motion.

CONCLUSION

The Board members have not yet had the opportunity to engage in any discovery. They need discovery on their justiciability argument, their takings defenses, and the injunctive-relief factors. Denying the Board members discovery would deprive them of a fair chance to respond to PhRMA's summary-judgment motion. As such, the Board members respectfully request that the Court deny the motion as premature or continue the hearing and briefing on the motion to allow the Board members time to take discovery.

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Respectfully submitted,

KEITH ELLISON
Attorney General
State of Minnesota

s/**Sarah Krans**
SARAH L. KRANS
Assistant Attorney General
Atty. Reg. No. 0338989

ANGELA BEHRENS
Assistant Attorney General
Atty. Reg. No. 0351076

445 Minnesota Street, Suite 1400
St. Paul, Minnesota 55101-2131
(651) 757-1273 (Voice)
(651) 297-1235 (Fax)
sarah.krans@ag.state.mn.us
angela.behrens@ag.state.mn.us

ATTORNEYS FOR DEFENDANTS

|#5540675-v1