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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA and

BIOTECHNOLOGY INNOVATION ORGANIZATION,

Plaintiffs,

vs.

BRIAN SANDOVAL, in his official capacity as Governor of the State of Nevada, and

RICHARD WHITLEY, in his official capacity as Director of the Nevada Department for Health and Human Services,

Defendants.

Case No.: 2:17-cv-02315-JCM-CWH

PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION, AND SUPPORTING MEMORANDUM OF POINTS AND AUTHORITIES

EXPEDITED TREATMENT REQUESTED (RELIEF NEEDED BY OCTOBER 1, 2017)

ORAL ARGUMENT REQUESTED

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MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Plaintiffs Pharmaceutical Research and Manufacturers of America ("PhRMA") and Biotechnology Innovation Organization ("BIO") hereby move pursuant to Federal Rule of Civil Procedure 65 for a temporary restraining order requiring Defendants Brian Sandoval, in his official capacity as Governor of the State of Nevada, and Richard Whitley, in his official capacity as Director of the Nevada Department of Health and Human Services (together, "Defendants"), to immediately cease and desist all action implementing or enforcing Sections 3.6–4, 4.3, 6, 7, 8, 9, and all related sections or subsections of Nevada Senate Bill No. 539 ("SB 539" or the "Act"), which will impose irreparable injury on Plaintiffs beginning on October 1, 2017—the date that the challenged provisions of SB 539 go into effect. Such a temporary restraining order will preserve the status quo until the Court can rule on Plaintiffs' motion for a preliminary injunction. Pursuant to Rule 65(b), sufficient grounds exist to issue a temporary restraining order. Plaintiffs further move for a preliminary injunction barring implementation or enforcement of the Sections of the Act identified above. Should this Court not enter a temporary restraining order, Plaintiffs ask the Court to set a briefing schedule on the motion for a preliminary injunction allowing sufficient time for a ruling before October 1, 2017. Defendants were notified of Plaintiffs' intent to seek preliminary injunctive relief on August 25, 2017. Through the meet and confer process since then, the parties' counsel discussed a potential resolution to avoid this motion, but on September 12, 2017, Defendants' counsel advised that Defendant Sandoval would prefer that Plaintiffs proceed with the filing of a motion.

In support of this motion, Plaintiffs respectfully submit the accompanying memorandum of points and authorities, affidavits, and exhibits detailing the grounds entitling them to relief.

Dated this 13th day of September, 2017.

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By: /s/ *Pat Lundvall*

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STATUTES

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MEMORANDUM OF POINTS AND AUTHORITIES

INTRODUCTION

Plaintiffs bring this action to prevent Nevada Senate Bill No. 539 ("SB 539" or the "Act," attached as Ex. A) from inflicting serious, nationwide injuries. This unprecedented, overreaching, and unconstitutional statute undermines federal law, devalues intellectual property, and dictates patent and trade secret protection to the entire nation. The challenged provisions of SB 539 will irreparably harm Plaintiffs' members who invent and manufacture diabetes drugs. Plaintiffs therefore seek a temporary restraining order and preliminary injunction barring implementation or enforcement of those provisions.

SB 539, signed on June 15, 2017, is novel in scope, ambition, and nationwide effect. As a penalty for exercising rights protected under the U.S. patent laws, SB 539 strips pharmaceutical manufacturers of trade secret protection for confidential, competitively sensitive, proprietary information regarding the production, cost, pricing, marketing, and advertising of their patented diabetes medicines. The Act then requires manufacturers to disclose this information to the Nevada Department of Health and Human Services (the "Department"), which must publish some of the information on its website and can disseminate the rest as it sees fit.

SB 539 violates the Constitution in at least four ways. *First*, SB 539 conflicts with federal patent law, including the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act") and is thus invalid under the Supremacy Clause. Federal law allows a patent holder to exclude others from making, using, or selling new inventions. For pharmaceuticals, the Hatch-Waxman Act adapts this system to ensure broad access to affordable medicines while offering innovators economic incentives sufficiently potent to surmount the enormous costs and risks of developing new treatments. SB 539 upsets this legislative balance by burdening a patent holder's right to set prices reflecting the incentives the federal patent laws provide.

Second, SB 539 is also preempted by federal trade-secret law. Recognizing that trade secrets are critical to U.S. businesses, Congress enhanced existing state-law safeguards by enacting the Defend Trade Secrets Act of 2016 ("DTSA"). The DTSA sets a federal baseline for trade-secret

protection. SB 539 not only falls below this baseline; it effectively nullifies federal protection for trade secrets, undermining innovation and competition in the American pharmaceutical industry.

Third, SB 539 violates the Takings Clause of the Fifth Amendment by depriving affected manufacturers of trade-secret protection, forcing them to disclose confidential information to the State, and mandating its dissemination on the Internet. Before SB 539, every state, including Nevada, treated these materials as trade secrets. They are property, and SB 539 destroys their value without recompense. It thus takes manufacturers' property "without just compensation."

Fourth, SB 539 violates the dormant Commerce Clause because the penalty it imposes in Nevada impairs interstate commerce. By tying penalties to the national benchmark price for a drug, SB 539 affects drug prices nationwide, even for transactions entirely outside Nevada. The abrogation of trade-secret protection likewise extends to every state. Rescinding trade-secret protection, mandating disclosures, and requiring online publication of information destroys its confidentiality—everywhere. Such disclosures cannot be undone—information cannot be undisclosed. SB 539 overrides the laws of other states protecting the information as trade secrets, including states where the affected manufacturers reside, pay taxes, and employ thousands. Only Congress can override state trade-secret law or impose national economic policies. Nevada cannot.

These issues are not only ripe, but urgent. The Department plans to publish its list of "essential" diabetes drugs on October 15, 2017, stripping away trade-secret protection and raising the risk of misappropriation. The Act also compels disclosures that will undermine manufacturers' ability to compete. *See* Veto Letter from Gov. Sandoval to Sen. Maj. Leader Ford (June 2, 2017), at 2-3 ("Veto Letter," attached as Ex. B). The harm to Plaintiffs' members and the public far outweighs any inconvenience to Defendants from delayed implementation of SB 539. And maintaining the status quo while this Court considers the constitutional issues is in the public interest. Plaintiffs therefore ask the Court to temporarily restrain Defendants from implementing or enforcing the challenged provisions of SB 539 pending resolution of Plaintiffs' motion for a preliminary injunction, and that the Court enjoin such implementation or enforcement pending resolution of this action.

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BACKGROUND

A. Plaintiffs' Members Spend Billions Each Year Developing Innovative Diabetes Medicines in Reliance on Patent and Trade-Secret Protections

More than 30 million Americans live with diabetes. An additional 84 million have pre-diabetes, with blood sugar levels higher than normal, increasing the risk they will develop diabetes. The disease is the seventh leading cause of death in the United States. It is, in short, an epidemic.[1]

Before 1922, a diagnosis of diabetes was a swift death sentence. Even with a strict diet, a patient typically survived "no more than three or four years," with miserable quality of life.[2] Blood vessel and nerve damage resulted in dizziness and fainting, sexual issues, frequent urination, blindness, kidney failure, and infections leading to amputation. In 1921, two scientists were able to reverse diabetes in dogs by injecting them with insulin from the pancreatic islets of healthy dogs.[3] The following year, Eli Lilly began mass producing early animal-based insulins, which allowed many patients to manage their diabetes.[4]

Since then, pharmaceutical manufacturers have devoted enormous resources to improving insulin treatment and controlling diabetes. They have produced human insulin and developed other ways to treat diabetes and to reduce its risks. They have made diabetes medication easier to use, increasing patients' adherence to their prescribed dosing, thereby reducing emergency room visits and hospitalizations, saving $8.3 billion a year.[5] Since 2000, FDA has approved 39 diabetes medicines. *See* Ex. C, Chart of FDA-Approved Diabetes Medicines; Compl. ¶ 24.

Despite these advances, 1.7 million Americans a year receive a new diagnosis of diabetes. Developing innovative new diabetes treatments and improving existing ones requires continuing

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[1] *See Medicines in Development for Diabetes: A Report on Diabetes and Related Conditions*, PhRMA (2016) ("PhRMA 2016 Report"), https://tinyurl.com/ydfnrxq7.

[2] Diabetes Que., *Treating Diabetes: 1921 to the Present Day* (Nov. 2016), https://tinyurl.com/yaqszq7s.

[3] *See* Brian Wu, *History of Diabetes: Past Treatments and New Discoveries*, Med. News Today (May 2017), http://www.medicalnewstoday.com/articles/317484.php.

[4] *Id.*

[5] 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, 1836 (2012).

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research. In 2016 alone, more than 170 medicines for diabetes and related conditions were in development. *See* PhRMA 2016 Report. Most reflect a potential new approach to fighting the disease.[6] The development pipeline includes a potential "first-in-class" oral medicine for Types 1 and 2 diabetes, a fully recombinant monoclonal antibody to treat patients with newly diagnosed Type 1 diabetes, and a medicine for nephropathy (kidney damage) from Type 1 or 2 diabetes.

Diabetes research and development also focuses on prevention: top universities, hospitals, and pharmaceutical companies devote significant time and resources to developing a vaccine that could teach the immune system not to attack pancreatic beta cells (which produce insulin), thus preventing Type 1 diabetes. In fact, a trial at Massachusetts General Hospital aims not only to prevent Type 1 diabetes, but to reverse it in patients who have had the disease under 5 years.[7]

The cost of such innovation is staggering. It takes on average 10-15 years and $2.6 billion to develop a new medicine, with low odds of success. From 1988-2014, only 12% of drugs that entered clinical trials were approved for use. Manufacturers can invest billions of dollars each year in research and development only if they have an appropriate opportunity to recoup that investment through sales of the small fraction of products that make it to market.

B. History and Overview of Nevada Senate Bill 539

As in all states, the number of adults in Nevada with diabetes has skyrocketed over the last 20 years. In 1995, the diabetes rate for adults in Nevada was about 4.7%. Today, it is near 12.4%. An additional 787,000 people, 38.5% of Nevada's adult population, have pre-diabetes. Senate Bill No. 265 ("SB 265"), introduced in the Nevada Senate in February 2017, was "intended to address the rapidly increasing cost of diabetes care in Nevada." *Hearing on S.B. 265 Before the Sen. Comm. on Health & Human Servs.*, 2017 Leg., 79th Sess. 33 (Nev. Mar. 29, 2017) ("Mar. 29 Mins."). The bill's author "sincerely believe[d] increased transparency leads to decreased costs." *Hearing on S.B. 265 Before the Sen. Comm. on Health & Human Servs.*, 2017 Leg., 79th Sess. 5 (Nev. May 3,

[6] *See, e.g.*, Genia Long, Analysis Grp., *The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development* (July 2017) (69% of diabetes drugs in development were potential first-in-class medicines).

[7] *See* Andrew Curry, *Pathways to a Type 1 Vaccine*, Diabetes Forecast (July 2016), http://www.diabetesforecast.org/2016/jul-aug/vaccines.html.

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2017). SB 539 incorporated much of SB 265. As the legislative history of SB 265 shows, the State focused primarily on controlling the list prices of insulin and other patented diabetes medicines. Proponents of the bill complained that "competition has not led to lower [insulin] prices" and asserted that manufacturers would simply "tweak" insulin "to keep it under patent status, so the patent does not expire and become eligible for generic versions." Mar. 29 Mins. at 36; *see also, e.g.*, *id.* at 33 (noting antitrust allegations against insulin manufacturers); *id.* at 58–60 (discussion of patent protection). Referring to the patented medicines Janumet and Jardiance, one proponent argued that he "should not [have to] depend on [manufacturer] coupons on the Internet to offset the cost of diabetic medications." *Id.* at 45. Another explained that the bill was designed to "hit directly to the root of the problem" of high diabetes drug prices because "pharma will react accordingly with rebate dollars and trying to unwind what has been done" to "meet the terms of what [SB 265] puts out." *Id.* at 37 (testimony of managed care pharmacist).

SB 265 sought to control prices by, first, directing the Department to compile a list of prescription drugs "essential" for treating diabetes. SB 265 § 6. Second, it compelled the manufacturer to report to the Department specific cost and pricing information for each essential diabetes drug. *Id.* § 7(1). Third, it excluded this cost and pricing information from Nevada's definition of "trade secret," *id.* § 27.5(5), and required the Department to publish a report on the prices and how they affect health care spending in Nevada, *id.* § 7(2). Fourth, it directed manufacturers to provide 90 days' notice before increasing the national benchmark list price, known as the wholesale acquisition cost or "WAC," of any essential diabetes drug. *Id.* § 8.

On May 16, 2017, SB 539, also targeting list price increases for diabetes drugs, was introduced. Originally a "complement" to SB 265, *see Hearing on S.B. 265 Before the Sen. Comm. on Health & Human Servs.*, 2017 Leg., 79th Sess. 3 (Nev. May 26, 2017) ("May 26 Mins."), SB 539 also required that "Pharmacy Benefit Managers" (PBMs)—intermediaries between manufacturers and payers—disclose rebates received from manufacturers the prior calendar year. SB 539's author justified it as an effort to control prices, as the "retail price [of diabetes drugs] paid by patients is unpredictable and can escalate to unaffordable levels over short periods." *Id.*

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On June 2, 2017, Governor Sandoval vetoed SB 265 because it "pose[d] serious risks of unintended and potentially detrimental consequences for Nevada's consumer patients," including the risk "that access to critical care will become more expensive, more restricted, and less equitable." Veto Letter at 2. The bill, he wrote, "could cause more harm than good for Nevada's families." *Id.* Governor Sandoval concluded that "constitutional and other legal concerns" rendered the bill "problematic" and vulnerable to challenges based on "federal preemption, the Fifth Amendment's prohibition on uncompensated takings, and the Dormant Commerce Clause." *Id.* at 3.

On June 5, 2017, the Nevada Senate and State Assembly both passed SB 539, which, as amended, largely replicated the drug pricing and reporting provisions of SB 265 that the Governor had deemed constitutionally problematic. *See* Veto Letter at 2.[8] Nonetheless, on June 15, 2017, three days after his veto, the Governor signed SB 539. Like SB 265, it directs the Department to compile, by February 1 of each year, a list of prescription drugs "essential for treating diabetes." SB 539 § 3.6(1). While not defining "essential," the Act requires the list to include "all forms of insulin and biguanides" sold in the State. *Id.*[9] In August 2017, the Nevada State Primary Care Office distributed a draft list of "essential diabetes drugs" with 46 major drugs, including Afrezza, Byetta, Duetact, Farxiga, Humulin, Invokana, Janumet, Januvia, Jardiance, Lantus, Nesina, Novolog, PrandiMet, and Trulicity. *See* Ex. D, Draft List of Essential Diabetes Drugs.

Upon release of the final list, the Act requires drug manufacturers, by April 1 of each year, to submit to the Department a report that includes:

- "[t]he costs of producing the drug";
- "marketing and advertising costs" associated with the drug;
- profit "earned from the drug" and the amount of "total profit" attributable to it;
- the amount spent on "patient prescription assistance program[s]";

[8] The key exception was dropping the 90-day notice provision for increases in the WAC.

[9] Insulin and biguanides each lower blood glucose through different physiological mechanisms. *See Biguanides (Metformin) for Prediabetes and Type 2 Diabetes*, WebMD, http://www.webmd.com/diabetes/biguanides-for-type-2-diabetes.

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- the cost of "coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the manufacturer attributable to the redemption of those coupons and the use of those programs";
- the "wholesale acquisition cost of the drug," defined as "the manufacturer's list price for a prescription drug to wholesalers or direct purchasers in the United States, not including any discounts, rebates or reductions in price, as reported in wholesale price guides or other publications of drug pricing date";
- "[a] history of any increases in the wholesale acquisition cost of the drug" for the prior five years, "including the amount of each such increase expressed as a percentage of the total wholesale acquisition cost of the drug, the month and year in which each increase became effective and any explanation for the increase";
- "[t]he aggregate amount of all rebates" in Nevada; and
- other "information prescribed by regulation . . . for the purpose of analyzing the cost of prescription drugs . . . on the list."

SB 539 § 3.8.

Any manufacturer that increases the WAC of an "essential" diabetes drug by more than the "Consumer Price Index, Medical Care Component" ("CPI") during the preceding year, or by double the percentage increase in the CPI for Medical Care over the previous two years, also must disclose:

- "[a] list of each factor that has contributed to the increase";
- "[t]he percentage of the total increase that is attributable to each factor";
- "[a]n explanation of the role of each factor"; and
- "[a]ny other information prescribed by regulation."

Id. §§ 3.6(2), 4.

By tying these disclosures to the CPI for Medical Care, the Act penalizes manufacturers whose diabetes drug prices exceed the index. But the CPI for Medical Care is not based only on drug prices. It also reflects prices for professional and hospital services. Effective diabetes drugs reduce doctor and hospital visits and thereby lower the CPI for Medical Care. Thus, on this measure, the more effective the product, the tighter the constraint on its price.

Once manufacturers have submitted the disclosures required by Sections 3.8 and 4, the Department, by June 1 of each year, must analyze them and "report on the price of the prescription drugs that appear on the most current lists . . . , the reasons for any increases in those prices and the effect of those prices on overall spending on prescription drugs in this State." *Id.* § 4.3. The Department must post the report on its website, *id.* § 6(a)(5), organized to provide each

manufacturer "its own separate entry," *id.* § 6(b). SB 539 allows the Department to publish the information, share it widely, or use it for such purposes as negotiating rebates with manufacturers.

What is more, SB 539 expressly eliminates trade-secret protection for all the information manufacturers must disclose. *Id.* § 4.3. Specifically, the Act narrows the definition of "trade secret" in NRS 600A.030 to exclude "any information that a manufacturer is required to report pursuant to section 3.8 or 4 of [the Act], . . . to the extent that such information is required to be disclosed by [that] section[]." *Id.* § 9(5)(b). Failure to disclose the required information subjects the manufacturer to an administrative penalty of up to $5,000 per day. *Id.* § 8(2).

The provisions of SB 539 relevant to this lawsuit are effective immediately "for the purpose of adopting regulations and performing any other [necessary] administrative tasks . . . and on October 1, 2017, for all other purposes." *Id.* § 28(3). The Department intends to publish the first list of "essential" diabetes drugs on October 15, 2017.

C. SB 539's Harm to Plaintiffs' Members and Innovation of Diabetes Treatments

SB 539 would seriously harm Plaintiffs' members, including the largest U.S. manufacturers of diabetes medicines. Several members produce drugs on the Department's draft list of "essential" diabetes drugs. *Compare* Ex. D, *with* Ex. E, Decl. of Vanessa Broadhurst, at ¶ 4; Ex. F, Decl. of James Borneman, at ¶ 6; Ex. G, Decl. of Derek L. Asay, ¶ 4; Ex. H, Decl. of Patrick T. Davish, at ¶ 4; Ex. I, Decl. of Steve Albers, at ¶ 4; Ex. J, Decl. of Christine Marsh, at ¶ 4. None resides in Nevada. *See, e.g.*, Ex. F ¶ 3; Ex. I ¶ 3; Ex. J ¶ 3.

Eliminating trade secret protection allows competitors of affected manufacturers to freely use the confidential data the Act requires be disclosed showing a manufacturer's cost structure, resource allocation, and pricing practices. Such access by competitors could handicap that manufacturer in the marketplace. Ex. E ¶ 13; Ex. F ¶¶ 15, 20; Ex. G ¶ 13; Ex. H ¶ 13; Ex. I ¶ 13; Ex. J ¶ 13. Worse, the factors manufacturers consider and the methodologies they deploy in setting prices are similar from product to product. Thus, this prejudice could spread to competition involving non-diabetes products. Similarly, information on a manufacturer's costs and pricing formulas can prejudice the company's ability to negotiate with third-party payers, including Nevada

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itself, regarding purchases and rebates for all the manufacturer's products. Ex. E ¶ 12; Ex. F ¶¶ 14, 17; Ex. G ¶ 12; Ex. H ¶ 12; Ex. I ¶ 12; Ex. J ¶ 12.

The economic harm from SB 539 will be nationwide. Because the WAC is a national benchmark, SB 539's effective cap on a drug's WAC will apply nationwide. Similarly, the economic value of trade secrets withers in every state—including those where affected manufacturers reside—once Nevada makes the information public. The competitive harm from SB 539 will undermine the incentives that patents provide for Plaintiffs' members to invest in developing innovative diabetes medicines. Ex. E ¶¶ 16–18; Ex. F ¶¶ 19–22; Ex. G ¶¶ 16–18; Ex. H ¶¶ 16–18; Ex. I ¶¶ 14–15; Ex. J ¶¶ 16–18. Absent judicial intervention, SB 539 could force innovators to revise their current and future priorities for diabetes research and development.

ARGUMENT

"A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see also DiTech Financial LLC v. Am. West Vill. II Owners Ass'n*, No. 2:17-CV-2164, 2017 WL 3610559, at *1 (D. Nev. Aug. 22, 2017) (applying same standard for temporary restraining order). Under this Circuit's "serious questions" test, a temporary restraining order and preliminary injunction are also "appropriate when a plaintiff demonstrates that serious questions going to the merits were raised and the balance of hardships tips sharply in the plaintiff's favor." *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134–35 (9th Cir. 2011); *accord Johnson v. Nguyen*, No. 3:12-CV-00538, 2015 WL 105826, at *9 (D. Nev. Jan. 7, 2015).[10] The court must balance "competing claims of injury" and "consider the effect on each

[10] Although the Federal Circuit would hear any appeal in this case as a result of Plaintiffs' patent preemption argument, *see, e.g.*, *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1365 (Fed. Cir. 2001), Ninth Circuit law governs whether this Court should grant a temporary restraining order and preliminary injunction. *See Broadcom Corp. v. Qualcomm Inc.*, No. SACV 05-468, 2005 WL 5925584, at *2 (C.D. Cal. Oct. 19, 2005); *Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d 891, 894 (Fed. Cir. 1998).

party" of granting or withholding the requested relief. *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 542 (1987).

Plaintiffs' constitutional challenges to SB 539 will likely succeed on the merits. In stripping trade-secret protection from manufacturers of patented diabetes medicines, the Act conflicts with federal patent and trade-secret law, destroys valuable intellectual property without compensation, and imposes Nevada's economic policy on every other state. The loss of trade secrets is irreversible and will not only harm the affected manufacturers, but also weaken national competition and undermine incentives to develop diabetes medicines. This harm outweighs any possible inconvenience to Defendants from postponing the Act's implementation and enforcement.

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS

A. SB 539 Is Preempted By Federal Patent and Trade-Secret Law

The Supremacy Clause makes "the Laws of the United States . . . the supreme Law of the Land." U.S. Const. art. VI, § 1, cl. 2. "Thus, where Congress legislates within the scope of its constitutionally granted powers, that legislation may displace state law." *Pharm. Research & Mfrs. of Am. v. District of Columbia* (*PhRMA*), 406 F. Supp. 2d 56, 64 (D.D.C. 2005), *aff'd sub nom. Biotech. Indus. Org. v. District of Columbia* (*BIO*), 496 F.3d 1362 (Fed. Cir. 2007). Even where federal legislation does not explicitly preempt state law, "federal courts [must] inquire whether a[n] implied preemption exists." *Id.* And implied preemption exists, in the form of "conflict preemption," where compliance with both state and federal regulation is either a "physical impossibility," *id.* at 65, or "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

To determine whether a state statute poses such an obstacle, courts scrutinize both the legislature's purpose and the "law's actual effect." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 105 (1992); *accord BIO*, 496 F.3d at 1372 ("Our conflict inquiry is a searching one that ranges beyond the literal text of the statute."). In purpose and effect, SB 539 obstructs federal patent and trade-secret laws from achieving their goals. It is therefore preempted.

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1. SB 539 Conflicts with Federal Patent Law

The Constitution delineates Congress's paramount role in setting national patent policy, vesting Congress with the power to "secur[e] for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. The stated objective of this clause is to "promote the Progress of Science and useful Arts." *Id.*

Federal patent laws "promote . . . progress by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974). Thus, a patent holder may "'exclude all from the use of the protected process or product' and charge prices of its choosing, including supracompetitive prices." *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 400–01 (3d Cir. 2015) (quoting *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2231 (2013)); *see also Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964) ("The grant of a patent is the grant of a statutory monopoly . . . ."). Patent laws "suppl[y] a carrot in the form of economic rewards resulting from the right to exclude," and "the only limitation on the size of the carrot [of exclusivity] should be the dictates of the marketplace." *King Instruments Corp. v. Perego*, 65 F.3d 941, 950, 960 (Fed. Cir. 1995).

The federal patent system thus "embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989). "Congress, as the promulgator of patent policy, is charged with balancing these disparate goals. The present patent system reflects the result of Congress's deliberations. Congress has decided that patentees' present amount of exclusionary power, the present length of patent terms, and the present conditions for patentability represent the best balance between exclusion and free use." *BIO*, 496 F.3d at 1373.

Patent protection is critical to promote pharmaceutical research and development because discovering a successful new drug is exceedingly difficult, costly, and rare. By one estimate, "95% of the experimental medicines that are studied in humans fail to be both effective and safe. . . . [B]ecause so many drugs fail, large pharmaceutical companies . . . spend $5 billion per new

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medicine."[11] Research and development costs of just the drugs that are ultimately approved are, on average, $2.6 billion, "a 145% increase" over the past decade.[12]

To deal with the unique economic challenges of pharmaceutical research and development, Congress in the Hatch-Waxman Act, extended the patent term for pharmaceuticals to "create a significant, new incentive which would result in increased expenditures for research and development, and ultimately in more innovative drugs." H.R. Rep. No. 98-857(I), at 18 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2650 (Committee on Energy and Commerce); *see also BIO*, 496 F.3d at 1373. Balanced against the need for these incentives to innovate was the goal of increasing consumer access to affordable medication. *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001). To that end, the Hatch-Waxman Act permits generic versions of an innovator's drug after the patent exclusivity expires. Signing the bill, President Reagan reiterated that it "will promote medical breakthroughs and drug innovation by granting drug companies up to 5 more years of patent protection for new drugs. And this extension will help compensate for the years of patent life lost due to the time-consuming, but essential, testing required by the Food and Drug Administration." Presidential Statement on Signing S. 1538 Into Law, 20 Weekly Comp. Pres. Doc. 1359 (Sept. 24, 1984).

Relying on the incentives in the Hatch-Waxman Act, innovators boosted research and development spending from $3.6 billion in 1984 to more than $30 billion in 2001.[13] In 2016 alone, PhRMA members invested roughly $65.5 billion in discovering and developing new medicines.[14] For example, Novo Nordisk developed NovoLog, a rapid-acting insulin product and one of the most widely used diabetes drugs in the United States. Since launching NovoLog, Novo Nordisk has

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[11] Matthew Herper, *The Cost of Creating A New Drug Now $5 Billion, Pushing Big Pharma To Change*, Forbes.com (Aug. 11, 2013).

[12] Rick Mullin, *Tufts Study Finds Big Rise In Cost Of Drug Development*, Chem. & Eng'g News (Nov. 20, 2014).

[13] *See Recent Developments Which May Impact Consumer Access to, and Demand for, Pharmaceuticals: Hearing Before the Subcomm. on Health of the House Comm. on Energy and Commerce*, 107th Cong. (June 13, 2001) (statement of Rep. Barbara Cubin).

[14] Pharmaceutical Research and Manufacturers of America, PhRMA Annual Member Survey (Washington, DC: PhRMA, 2017, forthcoming).

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continued to invest in improving delivery of the treatment, with patented devices such as a special injection syringe, an injection button, and a dose-setting limiter. By enhancing the convenience and efficacy of treatment, such innovations reduce nonadherence and help patients control blood sugar. The balance struck in the Hatch-Waxman Act has spurred many other innovations in treating diabetes. *See* Compl. ¶¶ 23–28 (innovative diabetes products developed by Plaintiffs' members).

In *BIO*, the Federal Circuit found that federal patent law preempted legislation at odds with this careful balance. Plaintiffs there challenged a District of Columbia statute prohibiting pharmaceutical manufacturers from selling or supplying a "patented prescription drug that results in the prescription drug being sold in the District for an excessive price." *BIO*, 496 F.3d at 1365. The court held that the statute was a "clear attempt to restrain . . . excessive [drug] prices, in effect diminishing the reward to patentees in order to provide greater benefit to District drug consumers." *Id.* at 1374. Because Congress—and Congress alone—is the "promulgator of patent policy," federal patent law preempted the District's attempt to "re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Id.* at 1373–74.

Like the D.C. law invalidated in *BIO*, SB 539 "attempt[s] to restrain . . . excessive [essential diabetes drug] prices, in effect diminishing the reward to patentees in order to provide greater benefit to [Nevada] drug consumers." *Id.* at 1374. The Act punishes manufacturers if "essential" diabetes drug prices increase more than the "percentage increase in the [CPI for Medical Services] during" the prior year or "[t]wice the percentage increase [in that index]" over the prior two years. SB 539 §§ 3.6(2), 4. The punishment is compelled disclosure of additional confidential pricing information and loss of trade-secret protection for that information. *See supra*, p. 5. The only way a manufacturer can preserve trade-secret protection is by limiting its list price to the *de facto* cap. SB 539 thus restrains patent holders from exercising their right under federal patent law to set prices.

This is precisely why the Federal Circuit in *BIO* struck down the D.C. law, because it "shift[ed] the benefits of a patented invention from inventors to consumers." 496 F.3d at 1374. The D.C. law did so by prohibiting manufacturers from selling patented prescription drugs at "excessive prices." Nevada seeks to do so by penalizing manufacturers who, on its measure, excessively raise the price of essential diabetes drugs. Both methods of curtailing federal patent rights are

unconstitutional. The preemption analysis is the same whether a local law bans excessive prices and then imposes penalties for violating the ban, as the D.C. law did, or imposes penalties for ostensibly excessive prices without expressly banning them first. *See Perez v. Campbell*, 402 U.S. 637, 652 (1971) (states may not "nullify . . . unwanted federal legislation by simply . . . articulating some state interest or policy—other than frustration of the federal objective—that would be tangentially furthered by the proposed state law"); *cf. Sorrell v. IMS Health Inc.*, 564 U.S. 552, 565–66 (2011) ("[T]he Government's content-based burdens [on speech] must satisfy the same rigorous scrutiny as its content-based bans."). The dispositive question is whether the law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *BIO*, 496 F.3d at 1372 (quoting *Hines*, 312 U.S. at 67). In this respect, the laws in *BIO* and SB 539 are indistinguishable: both "stand[] as an obstacle to the federal patent law's balance of objectives as established by Congress" by "penalizing high prices . . . and thus limiting the full exercise of the exclusionary power that derives from a patent." *BIO*, 496 F.3d at 1374.

In many ways, SB 539 is even less compatible with Congress's comprehensive federal patent scheme than was the law in *BIO*. That law only curbed *future* price increases, barring sales of patented drugs at "excessive" prices. SB 539 does that *and* punishes manufacturers for *past* price increases. It singles out a class of private companies—makers of essential diabetes drugs—because Nevada deems their past prices excessive. *See, e.g.*, Mar. 29 Mins at 33, 36–37, 58–60; May 26 Mins. at 3. The Act requires these companies alone to disclose confidential, competitively critical, proprietary information detailing costs, pricing factors, advertising plans, and marketing strategies for their patented diabetes medicines. *See* SB 539 § 3.8. The Act also wipes out trade-secret protection for this information. *Id.* § 9. Like many retrospective penalties, SB 539 also has a prospective effect. It deters the enormous investment needed to develop new diabetes medicines, because when manufacturers seek to recoup their investments by setting prices as federal patent law contemplates, the State will punish them for doing so. Thus, both retroactively and prospectively, SB 539 burdens pharmaceutical innovators' exercise of the right the federal patent laws confer.

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2. SB 539 Conflicts with Federal Trade-Secret Law

Federal and state trade-secret laws also play an important role in sustaining the American economy. Legal protection for trade secrets "encourage[s] invention in areas where patent law does not reach, and . . . prompt[s] the independent innovator to proceed with the discovery and exploitation of his invention." *Kewanee Oil*, 416 U.S. at 485. In the end, "[c]ompetition is fostered and the public is not deprived of the use of valuable, if not quite patentable, invention." *Id.*

Every U.S. state protects trade secrets. Forty-eight states, including Nevada, have adopted some form of the Uniform Trade Secrets Act ("UTSA"). *See* H.R. Rep. No. 114-529, at 4 (2016) (Committee on the Judiciary); *Frantz v. Johnson*, 999 P.2d 351, 357–58 (Nev. 2000). The remaining two states—New York and Massachusetts—protect trade secrets under the longstanding common-law tort of misappropriation. *See Ashland Mgmt. Inc. v. Janien*, 624 N.E.2d 1007, 1012 (N.Y. 1993); *Peabody v. Norfolk*, 98 Mass. 452, 457 (1868).

Against this backdrop, Congress passed the Defend Trade Secrets Act ("DTSA") of 2016, creating a federal private right of action for misappropriation of trade secrets "related to a product or service used in, or intended for use in, interstate or foreign commerce." Pub. L. No. 114-153, 130 Stat. 376 (2016) (codified at 18 U.S.C. § 1836(b)). Congress enacted the DTSA because "trade secrets are increasingly becoming the foundation of businesses across the country, with one estimate placing the value of trade secrets in the United States at $5 trillion. . . . With so much at stake, it is absolutely vital . . . [to] include strong protections against the theft of trade secrets." 162 Cong. Rec. H2028-01, H2033 (Apr. 27, 2016) (comments of Rep. Nadler). "By improving trade secret protection," Congress sought "to incentivize future innovation while protecting and encouraging the creation of American jobs." S. Rep. No. 114-220, at 3 (2016).

Even though all states protected trade secrets, Congress worried that state trade-secret "laws vary in a number of ways and contain built-in limitations that make them not wholly effective in a national and global economy." H.R. Rep. No. 114-529, at 4. The DTSA therefore provides U.S. businesses a uniform remedy for misappropriation because "trade secret cases often require swift action by courts across state lines to preserve evidence." *Id.* "[U]nlike patents, once this information is disclosed it instantly loses its value and the property right itself ceases to exist." 162 Cong. Rec.

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H2034 (comments of Rep. Jackson Lee). Thus, the DTSA allows businesses "to move quickly to Federal court . . . to stop trade secrets from winding up being disseminated and losing their value." H.R. Rep. No. 114-529, at 6; *see also id.* at 13; *accord* S. Rep. No. 114-220, at 3.

SB 539 frustrates Congress's purpose to provide an effective nationwide remedy for misappropriation of trade secrets. The Act compels manufacturers to disclose confidential information that derives independent value from not being generally known to third-party payers and competitors. Ex. E ¶¶ 6, 9; Ex. F ¶¶ 8, 11; Ex. G ¶¶ 6, 9; Ex. H ¶¶ 6, 9; Ex. I ¶¶ 6, 9; Ex. J ¶¶ 6, 9. This information is a trade secret under the DTSA as well as Nevada law—unless and until SB 539 takes effect.[15] *See, e.g.*, *Aerodynamics Inc. v. Caesars Entm't Operating Co.*, No. 2:15-CV-01344, 2015 WL 5679843, at *8 (D. Nev. Sept. 24, 2015) ("confidential pricing information, . . . marketing strategies, . . . exact pricing for [certain] bid[s], payment terms, and credits and discounts provided" held trade secrets under state law); *Finkel v. Cashman Prof'l, Inc.*, 270 P.3d 1259, 1263 (Nev. 2012) ("confidential pricing structures and marketing plans" were trade secrets); *see also* Compl. ¶ 86 (collecting additional cases). Further, as noted, the Act eliminates trade-secret protection for information that a manufacturer is required to report, SB 539 § 9, allows the Department to freely use or disseminate the disclosed information, and *directs* the Department to post a report matching the information to each manufacturer. *Id.* § 6(a)(5), (b).

Once published under the authority of SB 539, a manufacturer's information loses its trade-secret status not just in Nevada, but nationwide. Fundamental to the definition of a trade secret is that it remains confidential. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002 (1984) ("Because of the intangible nature of a trade secret, the extent of the property right therein is defined by the extent to which the owner of the secret protects his interest from disclosure to others."). Thus, information broadcast over the Internet has become "public knowledge" and no longer remains a trade secret.

[15] Because Congress modeled the DTSA definition of "trade secret" on the UTSA definition, "courts may look to the state UTSA when interpreting the DTSA." *Kuryakyn Holdings, LLC v. Ciro, LLC*, No. 15-CV-703-JDP, 2017 WL 1026025, at *5 (W.D. Wis. Mar. 15, 2017); *see also* H.R. Rep. 114-529, at 14 ("[T]he Committee does not intend for the definition of a trade secret to be meaningfully different from . . . [those] States that have adopted the UTSA.").

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Id.; *Philip Morris, Inc. v. Reilly*, 312 F.3d 24, 41 (1st Cir. 2002) (en banc) (it is "paradigmatic" that compelled disclosure to a party not required to keep the secret extinguishes the property right).

The difference between SB 539 and the DTSA (plus other states' laws) is not merely a matter of nuance. SB 539 guts the trade-secret protection afforded by the federal government and every state for confidential information associated with essential diabetes drugs. This mass nullification frustrates Congress's goal in the DTSA to enhance trade-secret protections and thereby to "incentivize future innovation while protecting and encouraging the creation of American jobs." S. Rep. No. 114-220, at 3. SB 539 thus "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines*, 312 U.S. at 67.

B. SB 539's Uncompensated Abolition of Trade-Secret Protection for Valuable Information Violates the Fifth Amendment Takings Clause

The Fifth and Fourteenth Amendments forbid the taking of "private property . . . for public use, without just compensation." U.S. Const., amend. V, XIV. "Private property" includes intangible property, such as trade secrets. *Ruckelshaus*, 467 U.S. at 1002–04. A state's "failure to provide adequate protection to assure [a trade secret's] confidentiality, when disclosure is compelled . . . , can amount to an unconstitutional taking of property by destroying [the trade secret], or by exposing it to the risk of destruction by public disclosure or by disclosure to competitors." *St. Michael's Convalescent Hosp. v. California*, 643 F.2d 1369, 1374 (9th Cir. 1981) (alteration omitted) (quoting *Wearly v. FTC*, 462 F. Supp. 589, 598 (D.N.J. 1978)).

In *Ruckelshaus*, the Supreme Court held that the Environmental Protection Agency (EPA) impermissibly took property without compensation by disclosing pesticide manufacturers' trade secrets collected under EPA's regulatory authority. 467 U.S. at 1016. A prior version of the statute had required EPA to keep confidential all information that manufacturers designated as trade secrets. *Id.* at 990–97. However, the revised statute authorized EPA to disclose this information to competitors for regulatory purposes so long as they agreed to pay for it and, if necessary, submit to arbitration over the price. *Id.* The Court held that this revision violated the Takings Clause because the manufacturer had disclosed the information with the expectation it would remain secret but then

found that the information was available to any competitor willing to arbitrate over the price. *Id.* at 1011; *see also Reilly*, 312 F.3d at 41–42; *St. Michael's*, 643 F.2d at 1374.

The Supreme Court explained that "[t]he right to exclude others is generally one of the most essential sticks in the bundle of [property] rights," and for trade secrets "the right to exclude others is central to the very definition of the property interest." *Ruckelshaus*, 467 U.S. at 1011. Under the revised statute, EPA (like Nevada) was "extinguish[ing]" trade secrets through public disclosure. *Id.* at 1002. Eliminating confidentiality, the essence of the property right, defeated manufacturers' investment-backed expectations. *Id.* at 1011–12. The expectations were reasonable because the information had trade-secret protection when generated. *Id.* at 1013; *Reilly*, 312 F.3d at 41. Disclosure destroyed its value as a trade secret. *Ruckelshaus*, 467 U.S. at 1012. Although the Court typically considered "several factors . . . when determining whether a governmental action has gone beyond 'regulation' and effects a 'taking'"—such as "the character of the governmental action, its economic impact, and its interference with reasonable investment-backed expectations," *id.* at 1005—the Court found the depredation of the manufacturers' investment-backed expectations dispositive because "the force of this factor [was] so overwhelming," *id.* In other words, this taking was "categorical." *Id.* at 1012; *see also Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1015 (1992) (destruction of core property interest is a categorical taking).

Like the statute at issue in *Ruckelshaus*, SB 539 extinguishes pharmaceutical manufacturers' property interest in the confidentiality of their trade secrets and thus works a categorical taking. Manufacturers investing in diabetes treatments had reasonable "investment-backed expectations" that their confidential information would remain secret. *See Reilly*, 312 F.3d at 40. For many years Nevada—like every other state—treated this information as a trade secret, with no diabetes exception. *See, e.g.*, Nev. Rev. Stat § 600A.030 (1987); *Finkel*, 270 P.3d at 1263; *Frantz*, 999 P.2d at 359. SB 539, however, strips trade-secret protection and *mandates* public disclosure of confidential information, eradicating trade-secret protection in other states. *See Ruckelshaus*, 467 U.S. at 1011–12; *see also* 162 Cong. Rec. H2034 ("[U]nlike patents, once this information is disclosed it instantly loses its value and the property right itself ceases to exist." (comments of Rep. Jackson Lee)). This is precisely the result that the Supreme Court held unconstitutional.

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The other two factors in the takings analysis, while cumulative, *see Ruckelshaus*, 467 U.S. at 1005; *Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978), reconfirm that the Act is an impermissible taking. First, the "character" of this legislative action weighs heavily against the Act. For punishment and coercion, it discloses trade secrets, causing them to "lose all value." *Reilly*, 312 F.3d at 41 (citing this aspect of state disclosure statute's "character" to show a regulatory taking). "Therefore, if the [pharmaceutical manufacturers] comply with the requirements of [SB 539], their property right will be extinguished." *Id.* at 42. "[T]his is precisely what the Takings Clause is designed to prevent." *Id.* at 43.

Second, eliminating trade-secret protection here will have a devastating "economic impact." Manufacturers of essential diabetes drugs, if forced to disclose such information, will be at a severe disadvantage vis-à-vis competitors not subject to the Act. *See supra*, p. 8. Affected manufacturers, but not manufacturers of non-diabetes drugs, also will be disadvantaged in dealing with third-party payers, who have the manufacturer's playbook in negotiations. *See supra*, p. 8.

These adverse effects extend beyond Nevada to the entire Nation. Ex. E ¶¶ 10–14; Ex. F ¶¶ 12–17; Ex. G ¶¶ 10–14; Ex. H ¶¶ 10–14; Ex. I ¶¶ 10–13; Ex. J ¶¶ 10–14. As noted, for trade secrets, disclosure anywhere is disclosure everywhere. *See supra*, pp. 8–9. A trade secret published in Nevada is useable in New York, Ohio, or any other state. This nationwide geographic scope amplifies the competitive harm to, and hence the penalty on, Plaintiffs' members for exercising the right federal patent law confers to set prices for their diabetes products. Manufacturers relied on the protection that the federal government, Nevada, and every other state afforded trade secrets. These companies did not expect Nevada to overturn that protection everywhere. Nor did they expect the consequent economic impact: the nationwide erosion of anticipated returns on their investments in researching, developing, and marketing their diabetes drugs. Ex. E ¶¶ 15–18; Ex. F ¶¶ 18–21; Ex. G ¶¶ 15–18; Ex. H ¶¶ 15–18; Ex. I ¶¶ 14–15; Ex. J ¶¶ 15–18.

C. SB 539 Violates the Commerce Clause by Overriding Every Other State's Laws

The Constitution authorizes Congress "[t]o regulate Commerce . . . among the several States." U.S. Const. art. I, § 8, cl. 3. The Commerce Clause "reflect[s] a central concern of the Framers . . . : the conviction that in order to succeed, the new Union would have to avoid the

tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation." *Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979). Thus, the Supreme Court has "long interpreted the Commerce Clause as an implicit restraint on state authority, even in the absence of a conflicting federal statute." *United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338 (2007). This is the "so-called 'dormant' aspect of the Commerce Clause." *Id.*

A state law oversteps these constitutional limits when it imposes a burden on interstate commerce "clearly excessive in relation to the putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). The dormant Commerce Clause "prohibits states . . . from regulating interstate commerce and enacting legislation that would 'offend sister States and exceed the inherent limits of the State's power.'" *PhRMA*, 406 F. Supp. 2d at 67 (quoting *Healy v. Beer Inst.*, 491 U.S. 324, 336 n.13 (1989)). SB 539 violates this principle by imposing sanctions for out-of-state conduct and nullifying rights that all other states grant.

First, SB 539 restrains PhRMA and BIO members' commerce in other states by penalizing them in Nevada. The Act's price cap is keyed to the WAC, a *national* benchmark. By affecting a drug's WAC, SB 539 affects drug prices *nationally*, including for drugs bought and sold outside Nevada. A New York manufacturer of essential diabetes drugs selling to a California purchaser must lower its price to prevent Nevada from negating the company's trade secrets. The dormant Commerce Clause bars Nevada from imposing such burdens on wholly extraterritorial commerce.

Again, *BIO* is instructive. Besides holding the D.C. law preempted by federal patent law, the district court found that the law's "impermissible extraterritorial reach" violated the dormant Commerce Clause. *PhRMA*, 406 F. Supp. 2d at 70. The court stressed that Plaintiffs' members "manufacture patented prescription drugs wholly outside the District of Columbia," are neither headquartered nor operate warehouses there, and make "the overwhelming majority of [their] sales" outside D.C. to out-of-state wholesalers. *Id.* at 68. "[T]he critical inquiry" was "whether the practical effect of the [law was] to control conduct beyond the boundaries of the State." *Id.* at 70 (quoting *Healy*, 491 U.S. at 336). It was indeed, as Plaintiffs' members could not "conduct commerce on their own terms elsewhere, without either scrutiny or control by the District." *Id.*

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The same is true of SB 539. By penalizing manufacturers for increasing the WAC of diabetes drugs above the CPI for Medical Care, SB 539 prevents them from "conduct[ing] commerce on their own terms elsewhere, without either scrutiny or control by [Nevada]." *Id.* Such a statute "offend[s] sister States and exceed[s] the inherent limits of [Nevada's] power." *Id.* at 67.

Second, SB 539 burdens interstate commerce by eviscerating commercial rights other states grant, stripping a broad compass of trade-secret protection for *all* manufacturers of essential diabetes drugs, whatever the prices they charge. *See* SB 539 §§ 3.8, 9. None of these companies is headquartered in Nevada. SB 539 will prevent manufacturers from protecting their trade secrets in every state. This imposition will interfere in particular with states that host these manufacturers' headquarters or key operations. Those jurisdictions have a legitimate interest—which Nevada overrides—in promoting the success of these manufacturers by protecting their trade secrets. *See Healy*, 491 U.S. at 336–37 ("[T]he Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State.").

For example, Eli Lilly—one of three major insulin manufacturers—is headquartered in Indianapolis, Indiana, with *no* offices or operations in Nevada. Indiana law protects Eli Lilly's trade secrets—including pricing and cost information for its essential diabetes drugs. *See, e.g.*, *Hydraulic Exch. & Repair, Inc. v. KM Specialty Pumps, Inc.*, 690 N.E.2d 782, 786 (Ind. Ct. App. 1998). Indiana has an interest in protecting that confidential information to preserve the company's financial strength, which affects local jobs and economic growth. In compelling the disclosure of information that is a trade secret under Indiana law, SB 539 overturns Indiana's protection. SB 539 bestows upon Nevada legislators supreme judgment as to the proper balance between the protection of trade secrets and the promotion of "transparency" in pricing. The dormant Commerce Clause does not tolerate such efforts by one state to foist its regulatory preferences on every other state.

These substantial effects on interstate commerce clearly exceed any putative local benefit SB 539 may have in Nevada. While the purpose of the Act is to control prices for diabetes drugs, neither the Act nor its legislative history explains how gutting manufacturers' trade-secret protection will lower prices—apart, that is, from impermissibly burdening manufacturers' lawful exercise of federal patent rights. *See, e.g.*, Mar. 29 Mins. at 33, 36–37, 58–60; May 26 Mins. at 3.

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Nevada's attempt to "extend [its] police power beyond its jurisdictional bounds" offends the dormant Commerce Clause. *C & A Carbone v. Town of Clarkstown*, 511 U.S. 383, 393 (1994).

II. PLAINTIFFS' MEMBERS WILL SUFFER IRREPARABLE HARM ABSENT A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTIVE RELIEF

"Irreparable harm is traditionally defined as harm for which there is no adequate legal remedy, such as an award of damages." *Ariz. Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1068 (9th Cir. 2014). It is "presumed where a party misappropriates a trade secret." *Excellence Cmty. Mgmt., LLC v. Gilmore*, 351 P.3d 720, 724 (Nev. 2015) (presumption where use of stolen trade secret was ongoing or imminent); *see also Finkel*, 270 P.3d at 1264; *Saini v. Int'l Game Tech.*, 434 F. Supp. 2d 913, 919 (D. Nev. 2006) ("[D]isclosure of confidential information or trade secrets would create irreparable injury . . . ."). "[I]t is axiomatic that unprotected disclosure of a trade secret destroys the secret." 4 Robert M. Milgrim & Eric E. Bensen, Milgrim on Trade Secrets § 15.02[1][c].

The challenged provisions of SB 539 become effective on October 1, 2017, and officially strip affected manufacturers of trade-secret protection for their confidential data as soon as the Department publishes its list of "essential" diabetes drugs, which Defendants represent will happen on October 15, 2017—just weeks from now. *See* SB 539 § 28(3). Furthermore, the Act compels disclosure no later than April 1, 2018. The Department then has free rein to disseminate the information. Faced with this forced disclosure, Plaintiffs' members must immediately reassess the risks and returns of their investments in diabetes therapies. *See* Ex. E ¶¶ 16–18; Ex. F ¶¶ 19–22; Ex. G ¶¶ 16–18; Ex. H ¶¶ 16–18; Ex. I ¶¶ 14–15; Ex. J ¶¶ 16–18. "[Such] harms, which are not readily addressed through payment of economic damages, are sufficient to meet the irreparable injury requirement for a preliminary injunction." *Saini*, 434 F. Supp. 2d at 919; *accord Aerodynamics*, 2015 WL 5679843, at *12. Only a temporary restraining order and preliminary injunction can prevent irreparable harm by protecting trade secrets pending resolution of this litigation.

III. THE BALANCE OF EQUITIES AND THE PUBLIC INTEREST SUPPORT A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

The balance of hardships decisively favors a temporary restraining order and preliminary injunction. Where, as here, a "plaintiff shows a substantial likelihood that the challenged law is

unconstitutional, no substantial harm to others can be said to inhere in its enjoinment." *Déjà vu of Nashville, Inc. v. Metro. Gov't of Nashville & Davidson Cty.*, 274 F.3d 377, 400 (6th Cir. 2001); *accord Nelson v. NASA*, 530 F.3d 865, 881–82 (9th Cir. 2008) (constitutional violation tips balance of hardships "sharply toward" party seeking injunction), *rev'd on other grounds*, 562 U.S. 134 (2011). Because Plaintiffs have shown a likelihood of success on their constitutional claims, the balance of hardships favors them, and the Court need not assess any potential effect on Defendants.

In any event, the only arguable "hardship" to Defendants is a possible delay in implementation of the Act. Even if publication of the list of "essential" diabetes drugs were postponed temporarily, any inconvenience resulting from the delay would pale compared to the substantial and irreparable harm that the Act would inflict on Plaintiffs' members.

Finally, the public interest strongly favors a temporary restraining order pending disposition of Plaintiffs' motion for a preliminary injunction, and a preliminary injunction pending resolution of this case. "[I]t is always in the public interest to prevent the violation of a party's constitutional rights." *Sw. Voter Registration Educ. Project v. Shelley*, 344 F.3d 882, 910 (9th Cir.), *rev'd on other grounds*, 344 F.3d 914 (9th Cir. 2003); *see also Preminger v. Principi*, 422 F.3d 815, 826 (9th Cir. 2005) (similar). And "there is a strong public interest in protecting trade secrets, as evidenced by the existence of the DTSA and UTSA." *Prot. Techs., Inc. v. Ribler*, 2017 WL 923912, at *3 (D. Nev. Mar. 8, 2017). Allowing SB 539 to take effect could undermine public health by upending Congress's carefully crafted a system of incentives encouraging the development of new medicines. It is therefore in the public interest to preserve the *status quo* while the Court considers SB 539's constitutional defects.

CONCLUSION

SB 539 interferes with federal patent and trade-secret laws, deprives manufacturers of property rights in their trade secrets, and improperly overrides the regulatory choices of every other state. These violations threaten irreparable harm to Plaintiffs' members, and ultimately, diabetes patients. Plaintiffs therefore respectfully ask the Court to temporarily restrain and preliminarily

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enjoin Defendants from implementing or enforcing Sections 3.6–4, 4.3, 6, 7, 8, and 9 of SB 539, and all related sections or subsections.

Dated: September 13, 2017.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I am an employee of McDonald Carano LLP, and that on this 13th day of September, 2017, I caused a true and correct copy of the foregoing **PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION, AND SUPPORTING MEMORANDUM OF POINTS AND AUTHORITIES** to be served via HAND DELIVERY upon the following:

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INDEX OF EXHIBITS

Description	Exhibit No.
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June 2, 2017 Letter from Gov. Sandoval to Sen. Majority Leader Ford	B
Chart of FDA-Approved Diabetes Medicines	C
List of Essential Diabetes Drugs	D
Declaration of Vanessa Broadhurst	E
Declaration of James Borneman	F
Declaration of Derek L. Asay	G
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