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State Action to Lower Prescription Drug Prices: Navigating Patent Preemption

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In the face of ever-rising health care costs, state policymakers continue to adopt new laws to curb the high cost of prescription drugs — from drug price-gouging protections to prescription drug affordability boards. This momentum, however, has been met with strong opposition from the pharmaceutical industry, which continues to challenge state prescription drug affordability laws in court.

Among other legal claims, the pharmaceutical industry regularly argues that state efforts to curb skyrocketing prescription drug prices are inconsistent with federal patent laws. Under the patent system, innovation is rewarded by giving the inventor the exclusive right to manufacture and sell a new drug or therapeutic for a certain period. Citing the importance of these exclusive rights in incentivizing the development of new therapies, the industry has claimed that state laws that curb high drug prices frustrate the operation of the federal patent regime and are thus preempted by federal law. This publication discusses recent litigation over federal patent law preemption and considerations for state policymakers when designing prescription drug affordability policies so that they may withstand judicial scrutiny.

This publication is part of a series on legal developments that state policymakers should consider when designing new policies to lower health care costs. This series also addresses considerations for state policymakers related to the Dormant Commerce Clause and preemption of state law by the Employee Retirement Income Security Act.

Background

Millions of people rely on prescription drugs to treat disease, improve health, alleviate suffering, and prevent death. Yet the high cost of prescription drugs jeopardizes access for many, forcing patients to make impossible decisions over whether to fill a prescription or ration the medication they need.[1] Medication nonadherence can have devastating effects on health, including worsening health outcomes and increased risks of morbidity and mortality.[2] It can also lead to higher overall health care costs due to complications.[3] And high prescription drug prices are an even greater barrier to access for patients with chronic conditions, low-income patients, and patients of color.[4] The high cost of prescription drugs is thus a public health and health equity issue.

Federal and state policymakers have taken several steps to lower prescription drug costs. At the federal level, Medicare has recently begun to negotiate prices for some of the costliest drugs, and Congress capped monthly cost-sharing for insulin at $35 per month for Medicare beneficiaries. Despite these targeted federal reforms, prescription drugs remain unaffordable for many, especially those with private health insurance who are not covered by programs, such as Medicare or Medicaid.

To fill some of these gaps, states have leveraged their traditional powers to protect health, safety, and welfare to address market failures and lower prescription drug costs for consumers. State-level policies have focused on price gouging, price transparency, cost-sharing caps on specific drugs (e.g., insulin), pharmacy benefit manager reform, and the creation of prescription drug affordability boards (PDABs), among other approaches.[5]

Preemption Under Federal Patent Law

State policymakers have adopted a range of policies to address these market failures and reduce sky-high prescription drug costs. But these efforts are often met with legal challenges from the drug industry, including claims that those state efforts are preempted by federal patent laws. Preemption is a doctrine founded in the U.S. Constitution's Supremacy Clause, which gives federal law primacy over state law. When federal and state laws conflict, state law must give way to federal law.

> "Implied preemption analysis does not justify a 'freewheeling judicial inquiry into whether a state statute is in tension with federal objectives'; such an endeavor **'would undercut the principle that it is Congress rather than the courts that preempts state law.'"**
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> *Chamber of Com. of U.S. v. Whiting*
> *563 U.S. 582, 607 (2011)*

The drug industry has argued that federal patent laws, such as the Patent Act and the Drug Price Competition and Patent Term Restoration Act, preempt state laws. The Patent Act gives patent holders "the right to exclude others from making, using, offering for sale, or selling the invention" for a specified period.[6] Congress also enacted the Drug Price Competition and Patent Term Restoration Act (also known as the "Hatch-Waxman Act"), which extends the duration of patents and provides other market exclusivities for pharmaceutical inventions while also making it easy for generics to enter the market.[7]

Neither the Patent Act nor the Hatch-Waxman Act expressly preempts state drug pricing laws, so lawsuits challenging state drug pricing laws rely on "implied" preemption. Under this doctrine, a state law can be preempted when Congress so thoroughly regulates or occupies a given field as to leave no room for state regulation. Federal law also impliedly preempts a state law that obstructs federal objectives or makes compliance with federal law impossible.

Because preemption limits state sovereignty, the Supreme Court has set a high bar for establishing implied preemption and cautioned that implied preemption should not be a "freewheeling judicial inquiry into whether a state statute is in tension with federal objectives."[8] For state laws regulating areas such as public health and consumer protection, there is a presumption *against* preemption that can be overcome only by showing that Congress clearly intended to preempt state laws.[9] Thus, when assessing implied preemption, courts fully examine the structure and purpose of a given federal law before concluding that a state law conflicts with Congress' clear purposes and objectives.[10]

Legal Challenges to State Drug Price-Gouging Laws

The drug industry has argued that state drug pricing laws are preempted by federal patent laws. Why? Because these state laws limit profits from patented drugs, which undermines the purpose of federal patent protections and market exclusivity. This argument was successfully used to challenge a price-gouging law adopted by the District of Columbia in 2005.

The District's law prohibited drug manufacturers from selling patented drugs in a way that resulted in "excessive" sales prices in the District. This restriction applied to drug manufacturers but not drug retailers. A drug was presumed excessively priced if its sales price was at least 30% higher than sales prices in Australia, Canada, Germany, or the United Kingdom — all high-income nations with their own patent protections and exclusivities. A drug manufacturer could rebut this presumption in court based on the cost of research and development to produce the drug, worldwide sales and profits, and the need to preserve local access to the drug for District residents. In other words, using foreign-market patent benchmarks, the District established a unique way of determining the appropriate compensation for pharmaceutical innovations — based on the same factors that underlie the U.S. patent system.[11] Drug manufacturers whose prices were found to be "excessive" could face civil penalties, damages, and injunctions.

The drug industry swiftly challenged this new law in court. In 2005, a federal district court agreed with the industry, concluding that the District's law was preempted by federal patent laws and violated the Commerce Clause.[12] In 2007, the Federal Circuit Court of Appeals affirmed this decision and held that the District's law was impliedly preempted by federal patent laws because it stood as an obstacle to achieving the goals of these requirements.[13]

Writing for a three-judge panel in *Biotechnology v. D.C.* (*BIO*), Judge Arthur J. Gajarsa explained that federal patent laws are designed to spur innovation by granting inventors a temporary right to exclude others from making, using, or selling their invention. By restricting competition, patent rights allow patent holders to earn "above-market profits" for the duration of the patent.[14] The District's price-gouging law, the court held, interfered with this federal patent regime by reducing the financial rewards that patents were meant to provide to drug manufacturers. The District's law did so by singling out patent rights, applying only to patented drugs, and linking the District's price caps to prices set by foreign patent regimes. Given this approach, the District's law was essentially a parallel "patent policy" that sought to "change federal patent policy within its borders," even though "the proper balance between innovators' profit and consumers' access to medication" is set exclusively by Congress.[15] In other words, the District's law impermissibly attempted to second-guess Congress's balance of trade-offs between incentivizing innovation and enabling access. Because the District's price-gouging law obstructed the achievement of federal patent law objectives, it was preempted.

While the pharmaceutical industry often cites *BIO* to challenge state drug pricing laws, the scope of that decision is narrow. *BIO* should not be read to suggest that all state laws that limit prescription drug prices are preempted. Even in invalidating the District's law, the *BIO* court made clear that state regulations that

affect patent holders' profits do not *per se* undermine federal patent protections. Rather, the *BIO* court held only that the District's unique price-gouging law, which targeted patented drugs in the specific ways noted above, impermissibly rebalanced federal patent trade-offs.[16] Judge Gajarsa affirmed as much, noting that "there is no express provision in the patent statute that prohibits states *from regulating the price of patented goods.*"[17]

Legal Challenges to Other State Consumer Protection Laws

The limited scope of the *BIO* decision notwithstanding, the drug industry still argues that state drug pricing laws are preempted by federal patent law. The industry does so even though the Supreme Court has made clear that Congress did not intend for federal patent laws to displace traditional state policy powers.[18] State consumer protection laws — including state laws that regulate the prices of goods[19] — fall under these traditional police powers where the Supreme Court has cautioned against implied preemption.

> **"Congress never intended that the patent laws should displace the police powers of the States,** meaning by that term those powers by which the health, good order, peace, and general welfare of the community are promoted."
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> ***Webber v. State of Virginia***
> ***103 U.S. 344 (1880)***

Recognizing this presumption against preemption, some courts have rejected the drug industry's arguments that federal patent law preempts state consumer protection laws. In *In re: EpiPen* — a class action lawsuit over drug manufacturers' anticompetitive marketing practices that caused consumers to pay inflated prices for EpiPens — a drug company argued that state consumer protection laws were preempted because they interfered with federal patent laws that gave the company the "exclusive right to make pricing decisions about its patented product."[20] A federal district court in Kansas rejected this argument, reasoning that federal patent rights do not "permit[] a patent holder to commit unfair and deceptive practices that violate state consumer protection laws."[21] The court found that the company had engaged in anticompetitive practices, such as "patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions,"[22] that deprived consumers of cheaper generic versions of EpiPen and other products that could have competed with EpiPen. Patent rights, the court concluded, did not insulate these practices from state regulation.

Patent-Based Challenges to State Pharmacy Requirements Under the 340B Program

The drug industry has also pointed to federal patent laws when attempting to invalidate state attempts to regulate the delivery of certain discounted drugs. Under the federal 340B program, drug manufacturers agree to offer their drugs to qualified providers at discounts as a condition of participating in Medicare and Medicaid. As this program has evolved, the use of contract pharmacies has become a prominent issue in disputes between drug companies and health care providers that participate in the 340B program.[23] To address concerns about abuses within the 340B program, several states have enacted laws requiring drug manufacturers to deliver drugs to pharmacies that contract with qualifying providers.

FEDERAL PATENT LAW AND THE MEDICARE DRUG NEGOTIATION PROGRAM

The drug industry's arguments about federal patent law have not been limited to legal challenges to state policies. In lawsuits challenging the federal Medicare drug price negotiation program, drug manufacturers have claimed that the new program's design and operation will undermine the "U.S. innovation ecosystem" of patent monopolies and "free-market forces."[24] These companies have argued that the Medicare drug negotiation program requires them to sell their drugs at negotiated prices, which deprives them of property rights conferred by patents.[25] To date, federal courts have rejected this argument, affirming long-standing case law that patent laws confer neither "a right to sell at all" nor "a right to sell at a particular price."[26]

The drug industry has challenged these laws, arguing that state laws requiring drug manufacturers to offer 340B drugs to contract pharmacies are preempted by federal patent laws. Drug manufacturers have claimed that patent laws preempt these state laws because the state laws "cap or fix the price at which patented drugs may be sold," thereby rebalancing the patent trade-offs, which diminishes the rewards of patent holders.[27]

Rejecting these arguments, courts have reasoned that such state laws do not "purport to lower prices on any drugs not already discounted under Section 340B" and, therefore, do "not substantially interfere with the incentives created by patent laws or other federal laws establishing regulatory exclusivities."[28] Indeed, Congress's own actions to limit drug prices — including through programs, such as 340B — undermine the drug industry's claim that Congress intended for federal patent laws to insulate patented drugs from general price regulation.

Making Sense of Federal Patent Preemption for State Prescription Drug Policy

Notwithstanding arguments made by the drug industry, states have the authority to adopt drug pricing laws without running afoul of federal patent laws. Why? Because federal patent laws do not prohibit states from regulating patented products or protecting the health and welfare of their citizens. In light of the presumption that federal patent laws do not impliedly preempt state consumer protection laws and the limited scope of the *BIO* decision, generally applicable state drug pricing laws should not be considered preempted by federal patent laws.

First, federal patent rights have not been construed as broadly as the drug industry claims. The Supreme Court has long recognized that federal patent laws do not confer an affirmative right to sell a drug; rather, these laws simply give a patent holder the right to exclude others from using the patent without permission.[29] Moreover, the drug industry's claim that state drug pricing laws interfere with Congress's design that drug prices be determined by the dictates of the market is belied by Congress's own efforts to curb the high cost of prescription drugs through programs, such as 340B, Medicaid rebates, and Medicare drug price negotiation.

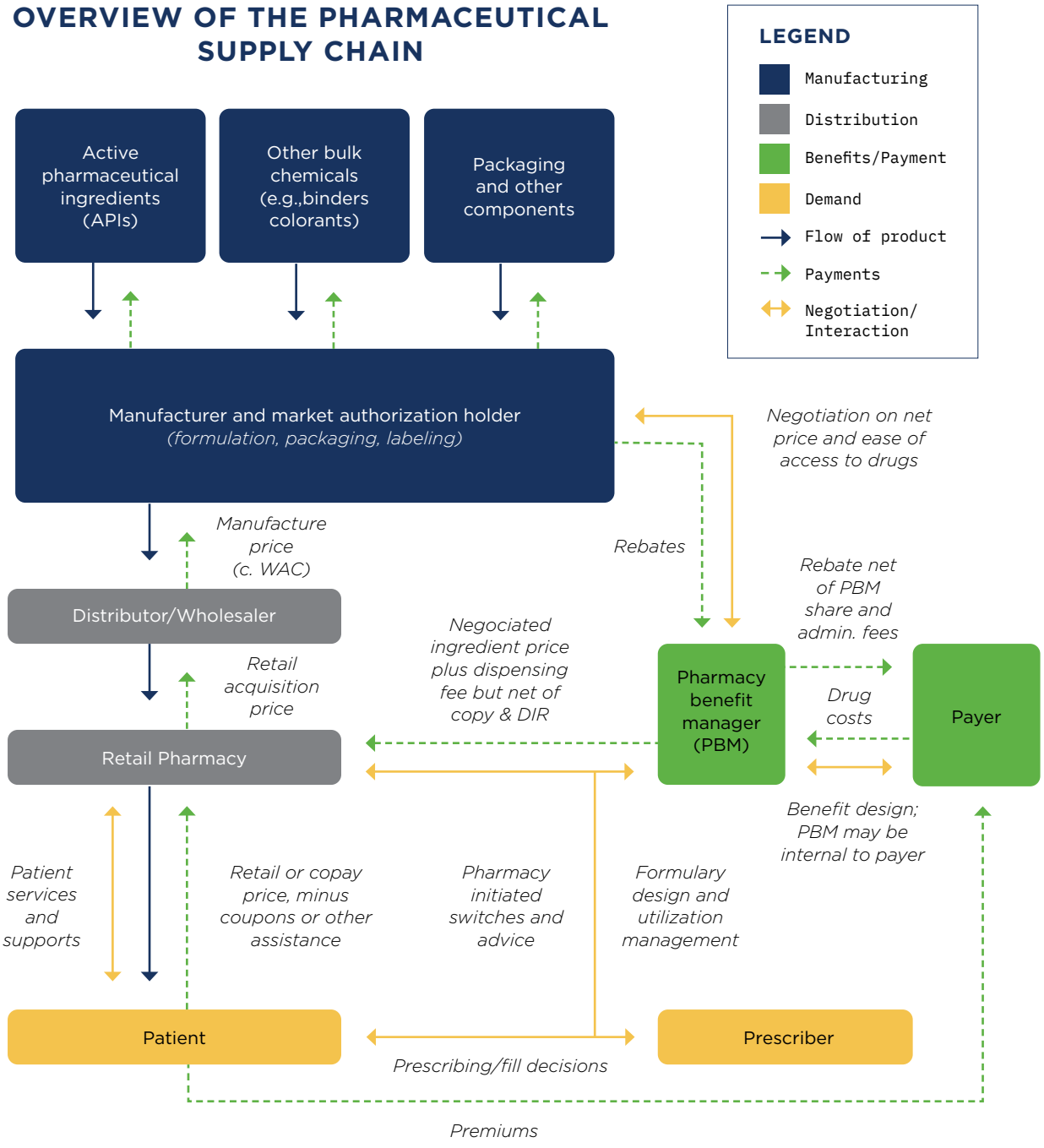
Second, as even the *BIO* court made clear, state laws that affect a drug manufacturer's profits do not *per se* undermine federal patent protections. Federal patent laws do not expressly preempt state laws that regulate the price of patented goods. While the drug industry has argued that federal patent laws impliedly preempt state drug pricing laws, the Supreme Court has set a high bar for reaching this conclusion by requiring a showing that Congress clearly intended for a federal law to override state laws. And the Court has expressly cautioned against the implied preemption of state laws enacted under a state's traditional police power, such as state public health and consumer protection laws.

Akin to the state laws at issue in *In re: EpiPen,* state drug pricing laws are consumer protection laws aimed at addressing market failures generated by the complex pharmaceutical supply chain. The pharmaceutical supply chain — and the various tactics used to manipulate prices within this supply chain — has contributed to high prescription drug prices and led to public health crises that states have sought to alleviate under their traditional police powers. Because drug manufacturers relinquish ownership of their patented product after the initial sale — at prices they set — it is hard to see how the regulation of downstream transactions diminishes or otherwise affects their patent rights. Although state drug pricing laws may affect the prices that patented drugs ultimately fetch in a regulated marketplace, those laws do not undermine Congress's balancing of patent trade-offs and therefore should not be preempted.

Take state PDAB laws. PDABs curb high drug prices by setting upper payment limits (UPLs) — the maximum amount that may be billed or paid for a prescription drug — within a state. Thus, UPLs typically apply to downstream transactions at in-state points of sale. Indeed, a federal district court in Colorado recently dismissed Amgen's challenge to Colorado's PDAB after concluding that Amgen, as an upstream actor that sits at the top of the supply chain, is not directly affected by the UPL and, thus, did not have standing to challenge the state law.[30]

In contrast to the District's price-gouging law in *BIO*, state PDAB laws are not targeted at patent rights and do not attempt to balance or otherwise set prices based on factors that interfere with the federal patent framework or incentives. Rather, PDABs determine affordability and set UPLs using market-based localized data (e.g., annual insurance expenditures, out-of-pocket costs for patients, level of competition, rebates, etc.) — and do not attempt to establish parallel patent policies.[31] By squarely addressing drug-pricing-related market failures, PDABs are unlikely to be preempted by federal patent laws.

OVERVIEW OF THE PHARMACEUTICAL SUPPLY CHAIN



NOTES: c = circa; DIR = direct and indirect remuneration; WAC = wholesale acquisition cost. Arrows denote relationship involving the flow of product (black arrows), information or negotiation (yellow arrows), and payments (green dashed arrows).

Source: Office of the Assistant Secretary for Planning and Evaluation, Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships. (Oct. 14, 2021) https://aspe.hhs.gov/reports/prescription-drug-supply-chains.

Conclusion

In the absence of comprehensive federal action to address high drug costs, states can and will continue to take action — from price-gouging laws to PDABs. States that do so should be mindful of, and prepared to respond to, the pharmaceutical industry's efforts to derail those policies by arguing that these consumer protection laws are preempted by federal patent law.

ENDNOTES

1 Grace Sparks et al. Public Opinion on Prescription Drugs and Their Prices. KFF. October 4, 2024. https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/.

2 Marie T. Brown et al. "Medication Adherence: Truth and Consequences." The American journal of the medical sciences vol. 351,4 (2016): 387-99. doi:10.1016/j.amjms.2016.01.010. https://www.amjmedsci.com/article/S0002-9629(15)37996-9/fulltext.

3 *Id.*

4 Sparks, *supra* note 1.

5 National Academy for State Health Policy. State Laws Passed to Lower Prescription Drug Costs: 2017-2025. https://nashp.org/state-tracker/state-drug-pricing-laws-2017-2025/.

6 Pub.L. No, 82—593, 66 Stat. 792, 804; 35 U.S.C. § 154 (a)(1).

7 Pub.L. No. 98—417, 98 Stat. 1585; see Pfizer Inc. v. Dr. Reddy's Lab'ys, Ltd., 359 F.3d 1361, 1364 (Fed. Cir. 2004) ("The Hatch–Waxman Act balanced the term-extension benefit to patentees, with new benefits to generic producers.") *see also* Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 404–05, 132 S. Ct. 1670, 1676, 182 L. Ed. 2d 678 (2012)("[The Hatch-Waxman] amendments allow a generic competitor to file an abbreviated new drug application (ANDA) piggy-backing on the brand's NDA.").

8 Chamber of Com. of U.S. v. Whiting, 563 U.S. 582, 607 (2011).

9 Arizona v. United States, 567 U.S. 387, 400 (2012).

10 Hillman v. Maretta, 569 U.S. 483, 490-91 (2013).

11 *See* Biotechnology Indus. Org. v. D.C., 505 F.3d 1343, 1347 (Fed. Cir. 2007) (Garjasa, J., concurring in denial of panel rehearing and rehearing en banc); See also Pharm. Rsch. & Mfrs. of Am. v. D.C., 406 F. Supp. 2d 56, 67 (D.D.C. 2005), *aff'd sub nom*. Biotechnology Indus. Org. v. D.C., 496 F.3d 1362 (Fed. Cir. 2007) ("Ironically, the factors Congress weighed in calculating their system of rewards are the very same factors the Act requires manufacturers to litigate in Superior Court in response to a prima facie case.").

12 Pharm. Rsch., 406 F. Supp. 2d at 67.

13 BIO, 496 F.3d 1362 (Fed. Cir. 2007).

14 *Id*. at 1372.

15 *Id*. at 1374.

16 BIO. v. D.C., 505 F.3d 1343, 1348 (Fed. Cir. 2007) (Gajarsa, Cir. Judge, concurring in the denial of the petition for rehearing en banc).

17 *BIO, 496 F.3d* at, 1372. (Fed. Cir. 2007) (emphasis added).

18 Webber v. State of Virginia, 103 U.S. 344, 344–48 (1880).

19 *See* In re: EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig., 336 F. Supp. 3d 1256, 1333–34 (D. Kan. 2018); Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 165 (1989) ("Nor does the fact that a particular item lies within the subject matter of the federal patent laws necessarily preclude the States from offering limited protection which does not impermissibly interfere with the federal patent scheme."); See also, Pennell v. City of San Jose, 485 U.S. 1, 11 (1988) ("[W]e have recognized that the government may intervene in the marketplace to regulate rates or prices that are artificially inflated as a result of the existence of a monopoly or near monopoly.").

20 *In re: EpiPen*, 336 F. Supp. 3d at 1333.

21 *Id.*

22 *Id.* at 1334.

23 Brendan Pierson, Lawsuits pile up over state laws on discounts for hospitals' contract pharmacies. Reuters. June 3, 2024. https://www.reuters.com/legal/government/lawsuits-pile-up-over-state-laws-discounts-hospitals-contract-pharmacies-2024-06-03/.

24 *See, e.g.*, COMPLAINT Janssen Pharmaceuticals v. Becerra, ¶¶1-4, https://litigationtracker.law.georgetown.edu/wp-content/uploads/2023/07/Janssen_20230718_COMPLAINT.pdf

25 Zachary Baron & Andrew Twinamatsiko, "A Deep Dive Into Takings Clause Challenges to the Medicare Drug Negotiation Program," Health Affairs Forefront (Jul. 6, 2023), https://www.healthaffairs.org/content/forefront/deep-dive-into-takings-clause-challenges-medicare-drug-price-negotiation-program.

26 Zachary Baron & Andrew Twinamatsiko, "A Deep Dive Into Takings Clause Challenges to the Medicare Drug Negotiation Program," *Health Affairs Forefront* (Jul. 6, 2023), https://www.healthaffairs.org/content/forefront/deep-dive-into-takings-clause-challenges-medicare-drug-price-negotiation-program.

27 AstraZeneca Pharms. LP v. Fitch, 766 F. Supp. 3d 657, 664 (S.D. Miss. 2024); Novartis Pharms. Corp. v. Fitch, 738 F. Supp. 3d 737, 753 (S.D. Miss. 2024).

28 Novartis Pharms. Corp. v. Fitch, 738 F. Supp. 3d 737, 753 (S.D. Miss. 2024); *See also* Pharm. Rsch. & Manufacturers of Am. v. Murrill, No. 6:23-CV-00997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024).

29 Bloomer v. McQuewan, 55 U.S. 539, 549 (1852).

30 Amgen Inc. v. Mizner, No. 24-CV-00810-NYW-SBP, 2025 WL 947474, at *6-7. (D. Colo. Mar. 28, 2025).

31 *See, e.g.,* NASHP, Model Legislation: An Act to Reduce the Costs of Prescription Drugs by Establishing a Prescription Drug Affordability Board, https://eadn-wc03-8290287.nxedge.io/wp-content/uploads/2022/12/2022-PDAB-Model-Act_Form_080222-2.pdf.