No. 26-1543

In the United States Court of Appeals for the Seventh Circuit

EDWARD CAMARGO, JUDITH MANDEL, SIMONE NAZARETH, AND BONNIE GOLTZ,

Plaintiffs-Appellants,

v.

ABBVIE INC.,

Defendant-Appellee.

On Appeal from the United States District Court
for the Northern District of Illinois, Eastern Division
District Court No. 1:23-cv-02589 (Hon. John Robert Blakey)

BRIEF OF *AMICI CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF DEFENDANT-APPELLEE AND AFFIRMANCE

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Appellate Court No: No. 26-1543

Short Caption: Camargo v. AbbVie Inc.

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N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

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Attorney's Signature: /s/ David E. Korn Date: 6/5/2026

Attorney's Printed Name: David E. Korn

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the Pharmaceutical Research and Manufacturers of America states that it has no parent corporation and no corporation or publicly held company owns 10% or more of its stock. The Chamber of Commerce of the United States of America ("Chamber") states that it is a non-profit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber.

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INTEREST OF *AMICI CURIAE*[1]

Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the country's leading innovative biopharmaceutical research companies. PhRMA's members develop innovative medicines that transform lives and create a healthier world. PhRMA advocates in support of public policies to ensure patients can access and afford medicines that prevent, treat, and cure disease. PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.[2] PhRMA members produce medicines that are distributed to pharmacies and hospitals throughout the United States.

The Chamber of Commerce of the United States of America is the world's largest business organization. As the nation's leading advocate for business, the Chamber represents companies and professional organizations of every size, in every industry sector, and from every region of the country.

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[1] No counsel for any party authored this brief in whole or in part, and no entity or person, aside from *amici*, their members, or their counsel, made any monetary contribution intended to fund this brief's preparation or submission. The parties have consented to this filing.

[2] PhRMA, *Research and Development Policy Framework*, https://bit.ly/4mcoGn7 (last visited June 5, 2026).

An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

This case raises questions of critical importance for PhRMA and the Chamber, as the Plaintiffs' claims seek to transform state consumer-protection statutes into vehicles for judicial review of patented-drug pricing decisions, threatening to replace Congress's national patent bargain with state-by-state pricing litigation. Attempts by private plaintiffs to use state law to regulate the prices that manufacturers may charge for their products conflict with federal patent policy and raise serious Supremacy Clause concerns. The legality of such price-control efforts is of vital interest to the members of PhRMA and the Chamber.

INTRODUCTION

Companies invest billions of dollars in research and development—often on a single drug—in reliance on a promise: that if their R&D efforts result in a safe and effective new product that is approved by regulators, then they will be able to recoup their up-front investments, and generate resources for future research, via sales during a federally guaranteed period of exclusivity. Lawsuits like the one Plaintiffs brought here, if successful, would upend this federally protected regime and the patient benefits it makes possible.

Put simply, Plaintiffs' claims invoke state law to regulate manufacturers' pricing decisions during the period in which federal law guarantees their right to earn market-based returns. Depriving companies of the return on their investments that Congress sought to protect conflicts sharply with the core objectives of the federal patent laws. It also would diminish manufacturers' ability to fund ongoing research into new medicines. That risk intensifies if plaintiffs can pursue litigation under multiple states' laws, inviting a patchwork of judicial pricing restrictions that would inevitably obstruct the biopharmaceutical market, curtail innovation, and hinder patient access to new therapies.

As the district court concluded, these principles required dismissal of plaintiffs' claims. Courts have long recognized that, under the Supremacy Clause, state law may not "stand[] as an obstacle to the federal patent law's balance of objectives as established by Congress." *Biotech. Indus. Org. v. District of Columbia* ("*BIO*"), 496 F.3d 1362, 1374 (Fed. Cir. 2007). State-law efforts to regulate the pricing of patented medicines do exactly that, upsetting the balance that Congress has struck between reducing prescription drug costs and encouraging pharmaceutical innovation. A key part of Congress's effort to encourage innovation is ensuring that patent holders can recover the billions of dollars that they spend on research, development, and approval of each new drug so that they can continue developing new treatments and cures.

Plaintiffs cannot evade this result by disguising their request for a price control as a claim under state unfair-trade-practices provisions, nor by asserting that formulary-access rebates not alleged to violate any independent statutory or common-law duty are "unfair" unless paid directly to patients. These state unfair-practices laws are meant to protect consumers from deception or from anticompetitive practices that violate the antitrust laws—purposes that do not upset the careful balance

Congress drew with respect to patent rights. But as the court below recognized, converting these provisions into price-control statutes would fundamentally recalibrate the patent system and disrupt the balance Congress established.

This Court should affirm because the complaint seeks to impose state-law price constraints that are incompatible with the federal patent system and therefore are preempted, as Appellee argues as well. *See* Doc. 22 at 33-42. PhRMA and the Chamber offer this separate brief to highlight the critical importance of the protections Congress established in the patent laws, and the risks that litigation like this case poses to investments, innovation, and, ultimately, patient care.

ARGUMENT

The Court should affirm the decision below. Under its exclusive constitutional authority to define the scope of patents, Congress has adopted patent laws that reflect a deliberate and careful balance between encouraging innovation and supporting consumer access to patented products. Exercising that authority for pharmaceutical patents in 1984 and 2010, Congress established an exclusivity period in which companies can seek market-based returns on the substantial expenditures and risk-taking required for drug development.

The investments that those statutes unleashed have paid immense dividends for patients. Since 2000, nearly 900 new medicines have received FDA approval, and hundreds more are in the pipeline, including a wide array of orphan drugs to treat rare diseases with small patient populations.

State-law efforts to recalibrate the balance Congress struck in the patent laws—including this litigation—are preempted by federal law. As the Federal Circuit has held in its role as the exclusive court of appeals for patent-law cases, "[t]he underlying determination about the proper balance between innovators' profit and consumer access to medication . . . is exclusively one for Congress to make." *Biotech. Indus. Org. v. District of Columbia* ("*BIO*"), 496 F.3d 1362, 1374 (Fed. Cir. 2007). States may not attempt to "re-balance the statutory framework of rewards and incentives . . . in effect diminishing the reward to patentees in order to provide greater benefit to . . . drug consumers." *Id.*

In contravention of those principles, Plaintiffs' claims here effectively seek court-imposed price controls on patented drugs under state consumer statutes. The district court properly found those claims preempted by the federal patent laws. This Court should affirm.

I. Congress Established a Careful Balance of Objectives in the Patent Laws

Prescription drug development is a complicated, lengthy, risky, and expensive endeavor. Recognizing the need to incentivize innovation, Congress in 1984 passed the Drug Price Competition and Patent Term Restoration Act. The law, commonly known as the Hatch-Waxman Act, extended the period of patent exclusivity for drugs, while also speeding entry of generic competitors upon expiration of the patent. In 2010, Congress enacted the Biologics Price Competition and Innovation Act (BPCIA), which establishes a similar regime for biologics.

In the years since enactment of these laws, the federal patent regime has worked as intended. Because the federally protected period permits innovators the opportunity to earn market-based returns for products within the scope of their patents, investments in biopharmaceutical research have flourished. In 2024 alone, the industry spent more than $100 billion on research and development.[1]

Congress in the Hatch-Waxman Act, the BPCIA, and other federal patent laws thus struck a careful balance between encouraging innovation and

[1] PhRMA, *2025 PhRMA Annual Membership Survey* 3 tbl. 1 (July 14, 2025), https://bit.ly/43tk1VM.

reducing the price of prescription drugs. State-law claims aiming to disrupt that balance and second-guess Congress's judgment—as Plaintiffs' claims do here—are preempted and fail as a matter of law.

A. Recognizing the immense costs of pharmaceutical innovation, Congress granted patent holders exclusionary rights that permit market-based returns during the patent term

1. Article I of the Constitution vests Congress with the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. Patent laws encourage innovation by granting an inventor, for a limited time, the right to exclude others from making, using, offering for sale, selling, or importing the patented invention. 35 U.S.C. § 154(a)(1). That exclusionary right is valuable because it gives the patent holder the opportunity to seek market-based returns free from infringing competition. *See King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 400-01 (3d Cir. 2015). The opportunity to earn these returns during the period of patent protection is the incentive that the patent laws offer "to inventors to risk the often enormous costs in terms of time, research, and development" that are required to make

possible "the introduction of new products and processes of manufacture into the economy." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974).

In exchange for this right during the exclusivity period, "patent laws impose upon the inventor a requirement of disclosure." *Id.* The inventor must fully and clearly describe the invention and "the manner and process of making and using it" so that any person skilled in that art could replicate it. 35 U.S.C. § 112(a). Once the patent expires, others may enter the market and compete with the patent-holder, driving down the price of the product to competitive levels. *BIO*, 496 F.3d at 1373.

The federal patent scheme 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). As the Federal Circuit recognized in striking down a District of Columbia price-control statute in the *BIO* case, "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." 496 F.3d at 1373. "Congress has decided that the 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." *Id.*

2. Nowhere is that balance more important—and more carefully calibrated—than in the context of prescription medications. It takes billions of dollars, and many years of effort, to develop a single drug or therapeutic treatment. On average, a manufacturer will spend nearly $3 billion developing a single new medicine.[2] And research and development costs do not end with approval by the U.S. Food and Drug Administration (FDA); pharmaceutical manufacturers often undertake significant post-approval research as well, to help further ensure safety and efficacy and to refine drugs and their delivery systems to meet patient needs.[3]

Manufacturers developing new drugs also face incredibly long odds. Only one compound in 5,000 that enters preclinical testing will achieve FDA approval, a failure rate of 99.98%.[4] Among the small share of investigational

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[2] *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 25-26 (2016), https://bit.ly/30UAIdg.

[3] *Id.* at 26.

[4] Sandra Kraljevic et al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps. 837, 837 (2004), https://bit.ly/2Y2gwEK; *see also* Aroon D. Hingorani et al., *Improving the Odds of Drug Development Success Through Human Genomics: Modelling Study*, 9 Sci. Reps., No. 18911, at 2 (2019), https://bit.ly/4tPPOej (discussing failure rate of over 96%).

medicines that get as far as entering clinical trials, moreover, only 12% ever achieve approval by the FDA.[5] And of those approved, only one in five will ever generate revenues that exceed the average cost of developing a medicine.[6] In short, patent protection—and the right to earn a market-based return for drugs—is particularly necessary to incentivize innovators to undertake the extraordinarily difficult, costly, and rarely successful steps necessary to try to develop a new drug that gains FDA approval.

Understanding these challenges, Congress enacted the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), which reflects Congress's recognition of the hazards of the drug-development and FDA-approval process. H.R. Rep. No. 98-857, pt. 1, at 15-18 (1984). Appreciating that pharmaceutical manufacturers were not receiving the same protection as other inventors because the patent term for drugs first accrued and continued to run during the extensive FDA approval process, Congress "extend[ed] the amount of time for which [pharmaceutical] patents are issued to include some or all of the time required for a manufacturer to test a product for safety and

[5] DiMasi et al., *supra* note 2, at 22-23.
[6] John A. Vernon et al., *Drug Development Costs When Financial Risk is Measured Using the FAMA-French Three-Factor Model*, 19 Health Econ. 1002, 1004 (2010), https://bit.ly/4tY8RmW.

efficacy and to receive marketing approval." *Id.* at 19-20. The aim of patent-term restoration was to "create a significant, new incentive which would result in increased expenditures for research and development, and ultimately in more innovative drugs." *Id.* at 18.

The Hatch-Waxman Act also took account of the need for broad consumer access to medication by speeding and simplifying the process for approval and sale of generic versions of an innovator's drug *after relevant patent barriers are resolved*. Manufacturers hoping to introduce a generic version of a drug can rely on the branded drug's safety and efficacy studies to lower costs and reduce delay.[7]

3. What Hatch-Waxman did for patented and generic drugs, the BPCIA did for biologics and biosimilars. Biologics, or biological products, comprise a wide range of therapeutic products developed from "natural sources—human, animal, or microorganism—and may be produced by biotechnology methods."[8] A "biosimilar" is a version of a biologic that is "similar" to the reference product.[9]

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[7] *See* 21 U.S.C. § 335(j).
[8] U.S. Food & Drug Admin., *What are "Biologics" Questions and Answers*, https://bit.ly/4dsCEPA (last updated Feb. 6, 2018).
[9] *See* 42 U.S.C. § 262(i)(2).

In the BPCIA, as in Hatch-Waxman, Congress balanced incentives for innovation against the value of follow-on competition. Rather than authorize state-by-state price review of biologic medicines, Congress created an expedited pathway for approval of biosimilars when federal law permits market entry.[10] This carefully crafted framework provides incentives for innovators to invest in research and development of new lifesaving and life-enhancing treatments that will benefit patients, while also "get[ting] generic drugs into the hands of patients at reasonable prices—fast." *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (quoting *In re Barr Lab'ys, Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)).

B. Hatch-Waxman and the BPCIA have fostered decades of biopharmaceutical investment and progress

The Hatch-Waxman Act and the BPCIA have worked as intended. Their incentives have encouraged innovators to boost research and development spending, while also promoting massive growth in generic competition when periods of patent exclusivity expire. Before Hatch-Waxman was enacted, manufacturers were investing less than $10 billion per year in research and

[10] *See* Krista Hessler Carver, et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 Food & Drug L. J. 671, 807-08 (2010), https://bit.ly/4dvEjnG.

development.[11] In the past decade, PhRMA members have invested approximately $850 billion in the search for new treatments and cures, reaching about $100 billion per year from 2021-2024.[12] This investment accounts for 78.6% of *all* U.S. industry investment in the field.[13] And the industry employs over 408,000 research and development employees—more than any other U.S. industry.[14]

Biopharmaceutical industry innovation efforts have helped patients. Since 2000, nearly 900 new medicines have been approved by the FDA.[15] This includes significant progress in the development of therapies for rare diseases.[16] As of 2023, there were more than 700 orphan drugs in development, many by PhRMA members, for treatments for patient populations with rare cancers and genetic disorders.[17] In 2025, PhRMA members received FDA

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[11] Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* (Apr. 2021), https://bit.ly/4fCHaMK.
[12] PhRMA, *supra* note 1, at 3 tbl. 1.
[13] TEConomy Partners, LLC & PhRMA, *The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates* 4 (May 1, 2024), https://bit.ly/3RFZFpG.
[14] *Id.* (2022 estimate).
[15] PhRMA, *Future of Medicine*, https://bit.ly/42UI5AQ (last visited June 5, 2026).
[16] PhRMA, *2012-2021: A Decade of Innovation in Rare Diseases* 3-4 (Feb. 25, 2022), https://bit.ly/4dHcV4R.
[17] *Id.*

approval for 52 medicines, 50 percent of which were for orphan drugs.[18] These achievements reflect manufacturers' ongoing focus on sustained and substantial investment in developing treatments and cures, including for long unmet medical needs.[19]

II. State-Law Litigation Challenging Manufacturers' Drug Pricing Decisions Upsets the Delicate Balance Congress Created via Federal Patent Law

Plaintiffs' claims in this case effectively seek judicial review, on state-law grounds, of AbbVie's nationwide pricing decisions for its patented drugs. SA4-5. The district court properly dismissed those claims as preempted and meritless. SA17-20. Permitting them to proceed—and thereby giving the green light for actions like this one to proliferate across the country—would conflict with Congress's careful judgment in the patent laws and ultimately harm the patients who rely on pharmaceutical innovation.

1. The Supremacy Clause bars states from interfering with the balance of interests that Congress struck in the patent laws. That includes state law claims aimed at restricting the prices at which patented drugs may be sold. As

[18] Kristen Booze, PhRMA, *Advancing Patient Care: A Look at New Medicines Approved in 2025* (Jan. 30, 2026), https://bit.ly/4dtfdFV (noting also that 14 of the approvals were for oncology drugs).
[19] *See id.*

the Federal Circuit explained in the *BIO* decision, any state efforts to constrain patentholders' ability to realize the value of the exclusivity period are preempted because they seek to "re-balance the statutory framework of rewards and incentives . . . in effect diminishing the reward to patentees in order to provide greater benefit to . . . drug consumers." *BIO*, 496 F.3d at 1374. "The underlying determination about the proper balance between innovators' profit and consumer access to medication . . . is exclusively one for Congress to make," and state-law efforts to cap the price of patented products are "contrary to the goals established by Congress in the patent laws." *Id.*

Put another way, state law may not be leveraged, by legislatures or private plaintiffs, to constrain manufacturers' "opportunity" to take advantage of the benefit of exclusivity conferred by Congress "during the patent's term." *Id.* at 1372. Again, those basic principles of preemption apply equally whether the state-law interference is attempted through legislation (as in *BIO*) or via litigation claims like Plaintiffs' here. *Cf. Purcell v. Bank of Am.*, 659 F.3d 622, 624 (7th Cir. 2011) ("[A] federal statute preempts state common law to the same extent as it preempts state statutory law." (citing *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011))).

Although courts have found some state-law actions concerning sales and marketing of prescription drugs not preempted, the claims in those cases alleged unlawful conduct independent of pricing decisions. *See* SA18-20 (discussing *In re: EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, 336 F. Supp. 3d 1256 (D. Kan. 2018)). But stripped to the operative allegations, Plaintiffs' complaint here targets pricing decisions as such—and does not allege anticompetitive, deceptive, or other allegedly unlawful market conduct. As the district court reasoned in the decision below, Plaintiffs' allegations in the operative complaint "do not plausibly suggest any antitrust violation or any harm to competition," nor "any unfair, deceptive, untrue, or misleading advertising," nor any other "conduct [that] is unlawful or fraudulent." SA13 (discussing California law); *see* SA16 (Connecticut law). Instead, Plaintiffs challenge only the "prices" that "AbbVie charged," without more, which means that their state-law claims are necessarily preempted by federal patent law. SA4.

Plaintiffs' effort to distinguish the Federal Circuit's *BIO* decision fails. Plaintiffs argue that their state consumer-protection claims are distinguishable from the District of Columbia law *BIO* considered because the consumer laws govern "conduct," while the D.C. provision addressed pricing.

Br. 37. That argument fails for two reasons. First, the *BIO* court's holding sweeps more broadly than Plaintiffs claim: any state law purporting to "limit[] the full exercise of the exclusionary power that derives from a patent" is preempted. 496 F.3d at 1374. Second, even if there were some distinction between "pricing" and "conduct" discernible in *BIO*, and none appears, such a distinction would be irrelevant here because, as just explained, Plaintiffs' claims attack only pricing decisions. Thus, *BIO* is directly instructive: Plaintiffs' labels differ, but the operative effect is the same—state-law review of whether a patented medicine's price is too high.

Plaintiffs also argue the district court improperly dismissed the complaint for failing to state a claim under "the federal antitrust laws," which Plaintiffs say is "not the standard." Br. 29 (citing SA12-13). That mischaracterizes the decision. The discussion that Plaintiffs criticize concerned *California* law, not federal law, and addressed Plaintiffs' claims under two California statutes. *See* SA12-13. Applying California case law holding that the state's Unfair Competition Act prohibits "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising," the court found that Plaintiffs alleged only "unfair" conduct, "which means they must 'show the conduct threatens an incipient

violation of an antitrust law or violates the policy or spirit of one of those laws because its effects are comparable to or the same as a violation of the law, or otherwise significantly threatens or harms competition.'" SA13 (quoting *Durell v. Sharp Healthcare*, 108 Cal. Rptr. 3d 682, 696, 690 (Cal. Ct. App. 2010)). Because the complaint failed to plausibly allege a California antitrust violation, the district court correctly dismissed it. *See* SA13-14.

Plaintiffs then claim that the district court ignored allegations in their complaint that purportedly address areas other than pricing. Br. 12-13, 21-22. But Plaintiffs cite no portion of their pleading that the district court supposedly overlooked, instead pressing an array of new claims about supposedly unlawful acts by AbbVie and others that were not alleged below. Br. 22-25. The logical inference is that Plaintiffs now see the gaps in their complaint and seek to remedy them on appeal. But it goes without saying that "[a] plaintiff cannot amend [its] complaint in [its] appeal brief." *Cody v. Harris*, 409 F.3d 853, 859 (7th Cir. 2005) (quoting *Kennedy v. Venrock Assocs.*, 348 F.3d 584, 594 (7th Cir. 2003)); *cf. Bowlin v. Bd. of Dirs., Judah Christian Sch.*, 167 F.4th 469, 474-75 (7th Cir. 2026) (review of a Rule 12(b)(6) dismissal is limited to "the factual allegations in the complaint"). And even if Plaintiffs could salvage the deficient complaint with new arguments now, the allusions

to other potential theories of liability in their brief are merely "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," that "do not suffice" to state a claim under any state statute. *Toulon v. Continental Cas. Co.*, 877 F.3d 725, 734 (7th Cir. 2017) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

Plaintiffs' "kickback" label shows that Plaintiffs seek to regulate prices. Br. 16-19. Plaintiffs never explain how manufacturer rebate payments to pharmacy benefit managers (PBMs) violate any statutory or common-law duty. Instead, they identify "excessive drug pricing" as what makes these payments unlawful. Br. 27; *see also id.* at 29 ("consumers pay more than they should,") 30 (consumers "must … pay AbbVie's inflated price"), 33 (plaintiff "spent thousands"). But to adjudicate that claim would require the trier of fact to make a determination of what pricing is "excessive" for a given drug—which is precisely what the federal patent laws preclude a state from doing.

2. Because this case seeks court-imposed drug price controls under state law, it is barred by the federal patent regime that Congress established. A necessary predicate to prevailing on Plaintiffs' theory is that the balance struck by Congress between innovation and access is wrong: According to the complaint, pharmaceutical manufacturers should not be entitled to set their

own prices during the statutory patent term, regardless of the disincentives that price controls would impose for research and development of new drugs. This sort of private second-guessing of Congress's balancing of priorities is exactly what the Supremacy Clause forbids. Plaintiffs are engaged in a "clear attempt to restrain" manufacturers' pricing decisions, "diminishing the reward to patentees in order to provide greater benefit to [some] consumers." *BIO*, 496 F.3d at 1374. The result is "contrary to the goals established by Congress in the patent laws," which only "Congress, as the promulgator of patent policy, is charged with balancing." *Id.* at 1373-74.

The United States leads the world in research and development for lifesaving treatments and cures precisely because its healthcare system relies on the strengths of market competition to balance cost-control, patient access, and continued innovation. More than half of all new drugs are launched first in the United States, with an average lag time of an entire year before being launched in other major industrial nations.[20] If state-law litigation attacking the pricing of patented drugs is allowed to proceed and proliferate, that would

[20] Andrew W. Mulcahy, *New Prescription Drugs Typically Sold First in U.S., Reach Other Wealthy Nations Within a Year*, RAND (Feb. 1, 2024), https://bit.ly/4ckxJgH.

pose a significant threat to America's leadership in making new drugs available to patients.

Litigation that successfully disrupts Congress's balancing of "the[] disparate goals" of federal patent policy would have a profound impact on innovation by signaling to manufacturers and investors that high-value drugs will face a lower return on investment. *BIO*, 496 F.3d at 1373. Innovation decisions by a manufacturer depend on the ability to earn market-based revenues following the massive investments and risk-taking required to develop new drugs.[21] Such revenues are, of course, contingent on pricing.[22] Court-imposed price controls, like the ones Plaintiffs seek here, would create less-favorable conditions for investment, almost certainly causing investors and researchers to scale back their efforts.[23] Investments in early-stage assets and biotechnology companies, which reflect an increasing share of the biopharmaceutical development pipeline, would be particularly affected.[24]

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[21] *See* Margaret E. Blume-Kohout et al., *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development*, 97 J. Pub. Econ. 327, 327 (2013), https://bit.ly/4f779Ma.
[22] *See id.*
[23] *See* Nicholas Bagley et al., *It's Time to Reform the Orphan Drug Act,* NEJM Catalyst (Dec. 19, 2018), https://bit.ly/4u6sY2b.
[24] *See* Ben Adams, *Biotechs Getting Bigger in Late-Stage R&D, Leaving Big Pharmas Behind: Report*, Fierce Biotech (Apr. 23, 2019),

Imposing price controls through litigation, even apart from its contravention of the federal patent laws, would ultimately harm the patients who rely on pharmaceutical innovation to develop new treatments for various cancers, rare diseases or, someday, hopefully Alzheimer's disease and other forms of dementia. Price controls would also distort the *kinds* of drugs that are developed going forward; certain therapeutic areas are riskier to invest in, and thus disproportionately affected by reductions in potential revenue. For example, investment in treatments targeting sensory organs, the nervous system, and antineoplastic and immunomodulating agents may be particularly sensitive to the size of the expected market for the treatment.[25] Treatments for conditions such as cancer and Alzheimer's disease, therefore, may be among the most likely to be adversely affected by state-law price controls.[26]

Plaintiffs here may have a different view than Congress about the right tradeoff between innovation and access. They may even dispute that market-based rewards during the period of patent exclusivity are necessary, or that price caps will hinder innovation. But for preemption purposes, it suffices that

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https://bit.ly/42VDnCL (discussing report from the IQVIA Institute for Human Data Science).

[25] Pierre Dubois et al., *Market Size and Pharmaceutical Innovation*, 46 RAND J. Econ. 844, 862 tbl. 8 (2015), https://bit.ly/4wP1K2E.

[26] *See id.*

Congress has established *this* tradeoff, "decid[ing] 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. Given that federal choice, private plaintiffs may not use state law to "re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Id.* at 1374.

CONCLUSION

For the foregoing reasons, the Court should affirm the judgment below.

Dated: June 5, 2026

Respectfully submitted,

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1. The foregoing Brief of *Amici Curiae* complies with the type-volume limitations of Seventh Circuit Rule 29 because the brief contains 4,679 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. This brief also complies with the typeface requirements of Seventh Circuit Rule 32(b) and the type-style requirements of Fed. R. App. P. 32(a)(6) because the brief has been prepared in a proportionally spaced typeface using Microsoft Word in Century Expanded BT 14-point font.

Dated: June 5, 2026

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I hereby certify that on June 5, 2026, I electronically filed the foregoing document with the United States Court of Appeals for the Seventh Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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